

# EPA R.E.D. FACTS

## Pesticide Reregistration

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for the Peroxy Compounds, including hydrogen peroxide, peroxyacetic acid, and potassium peroxyomonosulfate sulfate.

## Use Profile

The peroxy compounds are microbiocides. When mixed with water and applied by spraying, fogging or immersing, they kill bacteria, fungi and viruses on hard surfaces including equipment, floors and walls, indoors in agricultural premises, food establishments, commercial/industrial locations, hospital/medical institutions, and bathrooms in residences. Hydrogen peroxide and peroxyacetic acid products are formulated as liquids, and the one registered product that contains potassium peroxyomonosulfate sulfate is formulated as a solid soluble concentrate.

## Regulatory History

Hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate products were first registered in the United States as pesticides as early as 1977, 1985 and 1968 respectively, for use as disinfectants, sanitizers and sterilants. Currently, 23 products are registered which contain peroxy compounds as active ingredients; 11 products contain hydrogen peroxide, 11 products contain peroxyacetic acid, and one product contains potassium peroxyomonosulfate sulfate. Under a Memorandum of Understanding signed by EPA and the Food and Drug Administration in June 1993, EPA has primary regulatory jurisdiction over the peroxy compounds.

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## **Human Health Assessment**

### **Human Toxicity**

The three peroxy compounds are oxidizing agents. They can react, sometimes violently, with reducing agents, so in concentrated form they must be handled with care.

These compounds are corrosive and severely irritating to the eyes, skin and mucous membranes. They have been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for eye and dermal irritation. In contrast, they are not extremely toxic by the oral route, and are placed in Toxicity Category III for acute oral effects. It is because of their very reactive properties and moderately low oral toxicity that dilute concentrations of peroxy compounds have found wide applications and safe use as disinfectants.

Based on their chemical reactivity, the peroxy compounds are expected to have biological activity, particularly with molecules. Hydrogen peroxide, for example, is known to be mutagenic.

### **Dietary Exposure**

Hydrogen peroxide and peroxyacetic acid are used in dairy/cheese processing plants, on food processing equipment and in pasteurizers in breweries, wineries and beverage plants. Although food may come into contact with treated equipment, only trace amounts of the chemicals would remain on equipment, since both compounds degrade rapidly in air to form oxygen and water. No residues of these pesticides are expected to remain in food.

When potassium peroxyomonosulfate sulfate is used to disinfect poultry houses, hatcheries and processing plants, it does not come into direct contact with animals or food. The animals or meat/eggs are removed before use, which is followed by a potable water rinse and drying time before the animals or food are reintroduced. This is considered a non-food use and no dietary exposure is expected to result.

### **Occupational and Residential Exposure**

Applicators/mixers may be exposed to hydrogen peroxide and peroxyacetic acid when these chemicals are applied as sprays, wipe/mop-on or immersion solutions, to disinfect industrial/commercial floors, food processing equipment, pasteurizers, medical equipment or residential bathroom surfaces. When potassium peroxyomonosulfate sulfate is applied in poultry houses, hatcheries and processing plants by spraying, misting or fogging, dermal and inhalation exposure of applicators is expected. These exposures are of concern since the peroxy compounds are corrosive and severely irritating to the skin, eyes and mucous membranes. However, product labels require the use of protective equipment including protective clothing, rubber gloves, and goggles, a face shield or safety glasses. Labels also recommend thorough washing (including clothing) with soap and water

after handling. These measures sufficiently minimize exposure and risk to applicators/mixers.

#### **Human Risk Assessment**

Essentially no dietary exposure occurs from use of the peroxy compounds, so no dietary or chronic risks are posed. These chemicals are corrosive and pose acute toxicity risks of severe eye and skin irritation to applicators and mixers. These risks are minimized, however, through use of protective equipment, as required by product labeling. Therefore, the risks to humans are considered negligible.

### **Environmental Assessment**

#### **Environmental Fate**

The peroxy compounds are registered for indoor uses only. No direct environmental exposure is anticipated from their use as directed by product labeling.

#### **Ecological Effects**

Because of their indoor use patterns, and because they rapidly degrade to oxygen, carbon dioxide, water or acetic acid, avian and aquatic toxicity studies were waived for hydrogen peroxide and peroxyacetic acid.

Potassium peroxyomonosulfate sulfate is corrosive and is assumed to be highly toxic to birds on an acute oral basis. Avian dietary studies using the bobwhite quail indicate that the chemical is practically nontoxic to birds on a dietary basis. It is highly toxic to rainbow trout and moderately toxic to bluegill sunfish.

#### **Ecological Effects Risk Assessment**

All use patterns for the three peroxy compounds are considered indoor. Risks to wildlife are considered minimal since exposure is extremely low or nonexistent when the pesticides are used according to label directions.

### **Additional Data Required**

EPA is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSF), and revised product labeling for reregistration of products containing the peroxy compounds.

### **Product Labeling Changes Required**

The labeling of all end-use products containing the peroxy compounds must comply with EPA's current pesticide labeling requirements. In addition:

- Personal Protective Equipment (PPE) Requirements**

Labels of all end-use products for commercial, industrial and medical uses must require mixers and applicators to use protective equipment including protective clothing, rubber gloves, and goggles, a face shield or safety glasses. Labels also must recommend washing (including clothing) with soap and water after handling these pesticides.

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- Dilution Water pH Requirement

Labels of products containing potassium peroxyomonosulfate sulfate and sodium chloride salts must specify the appropriate pH range of dilution water, to ensure optimum and safe use.

## Regulatory Conclusion

The use of registered products containing the peroxy compounds will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration. These products will be reregistered once the required product-specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products also containing other active ingredients will be reregistered only when the other active ingredients are eligible for reregistration.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for the Peroxy Compounds during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the Peroxy Compounds RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the Peroxy Compounds RED, or reregistration of individual products containing peroxy compounds, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 8:00 am to 6:00 pm Central Time, Monday through Friday.

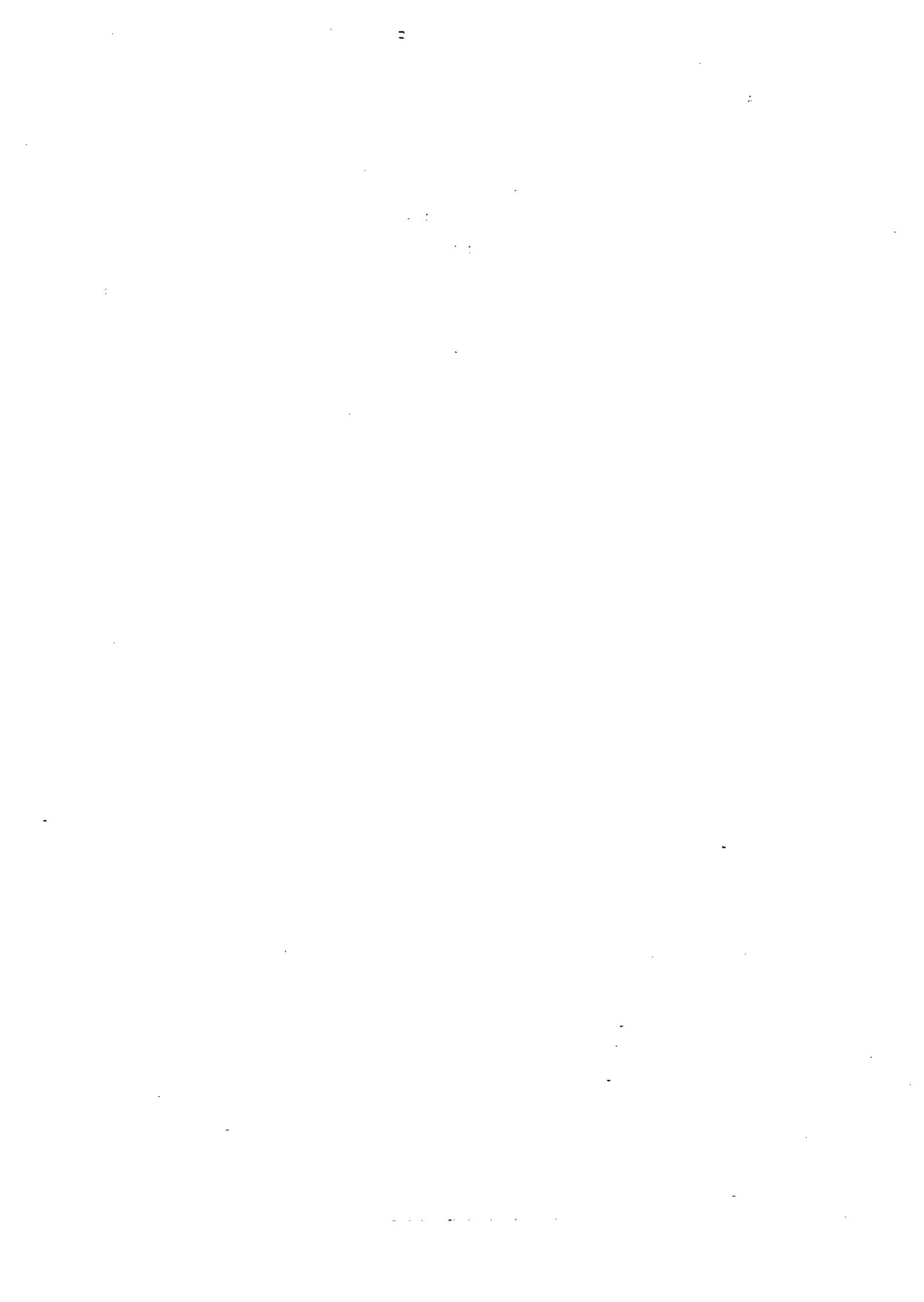
**REREGISTRATION ELIGIBILITY DECISION**

**PEROXY COMPOUNDS**

**LIST D**

**CASE 4072**

ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS  
SPECIAL REVIEW AND REREGISTRATION DIVISION



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# **PEROXY COMPOUNDS REREGISTRATION ELIGIBILITY DECISION TEAM**

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## **GLOSSARY OF TERMS AND ABBREVIATIONS**

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe as designated by FDA
HDT	Highest Dose Tested
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>lo</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

## **GLOSSARY OF TERMS AND ABBREVIATIONS**

<b>MOE</b>	Margin Of Exposure (PAD)
<b>MRID</b>	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
<b>N/A</b>	Not Applicable
<b>NPDES</b>	National Pollutant Discharge Elimination System
<b>NOEL</b>	No Observed Effect Level
<b>OPP</b>	Office of Pesticide Programs
<b>PADI</b>	Provisional Acceptable Daily Intake
<b>ppm</b>	Parts Per Million
<b>Q<sub>1</sub></b>	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
<b>RED</b>	Reregistration Eligibility Decision
<b>RfD</b>	Reference Dose
<b>RS</b>	Registration Standard
<b>TD</b>	Toxic Dose. The dose at which a substance produces a toxic effect.
<b>TC</b>	Toxic Concentration. The dose at which a substance produces a toxic effect.
<b>TMRC</b>	Theoretical Maximum Residue Contribution.

## **EXECUTIVE SUMMARY**

The Environmental Protection Agency has determined that the uses of hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration.

Before reregistering the products containing hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate, the Agency is requiring that product specific data, revised Confidential Statements of Formula, and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

Hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate are microbiocides. When mixed with water and applied by spraying, fogging or immersing, these chemicals kill bacteria, fungi and viruses on surfaces of treated materials. Currently, 23 products are registered that contain one or more of these peroxy compounds as the active ingredients: 11 contain hydrogen peroxide, 11 contain peroxyacetic acid, and one contains potassium peroxyomonosulfate sulfate.

## I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate, collectively referred to as "peroxy compounds". The document consists of six sections. Section I is the introduction. Section II describes these active ingredients, their uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for each active ingredient and Section V discusses the reregistration requirements. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## **II. CASE OVERVIEW**

### **A. Chemical Overview**

The following active ingredient(s) are covered by this Reregistration Eligibility Document:

**1. Common Name:** Hydrogen Peroxide

- **Chemical Name:** Hydrogen Peroxide
- **CAS Registry Number:** 7722-84-1
- **OPP Chemical Code:** 000595
- **Empirical Formula:** H<sub>2</sub>O<sub>2</sub>

**2. Common Name:** Peroxyacetic Acid

- **Chemical Name:** Peroxyacetic Acid
- **CAS Registry Number:** 79-21-0
- **OPP Chemical Code:** 063201
- **Empirical Formula:** C<sub>2</sub>H<sub>4</sub>O<sub>3</sub>

3. Common Name: Potassium Peroxymonosulfate Sulfate; Potassium Peroxomonosulfate Sulfate.
- Chemical Name: Potassium Peroxymonosulfate Sulfate (or Potassium Peroxomonosulfate Sulfate; The rules of chemical nomenclature state that both of these chemical names would be correct; however, peroxy is preferred).
  - CAS Registry Number: 37222-66-5
  - OPP Chemical Code: 63607
  - Empirical Formula:  $(\text{KHSO}_5 \cdot \text{KHSO}_4 \cdot \text{K}_2\text{SO}_4)$

## B. Use Profile

The following is information on the current registered uses of the peroxy compounds with an overview of use sites and application methods. A detailed table of these uses of hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate is in Appendix A.

### For Hydrogen Peroxide:

#### TYPE OF PESTICIDE:

Sterilant/Sporicide, Tuberculocide, Medical disinfectant, Broad spectrum disinfectant, Disinfectant (Bactericide/Germicide, General or Broad-Spectrum, Hospital or Medical), Sanitizer (Food and Non-food), Virucide, Fungicide.

#### USE SITES:

#### INDOOR FOOD:

Agricultural/Farm Premises; Dairies/Cheese processing plant equipment and premises; Livestock, including dairy cattle, dairy goats and poultry; Dairy farm milk handling

facilities and equipment, Dairy farm milking equipment; Food handling and food processing establishments and equipment.

#### INDOOR NON-FOOD:

Animals (Laboratory/Research); Commercial/Institutional/Industrial floors, premises and equipment; Eating Establishment Food Handling, Food Serving and Non-Food areas; Reverse osmosis water systems.

#### INDOOR MEDICAL:

Hospital Critical Items (Surgical Instruments/Pacemakers); Hospital Semicritical Items (Catheters/Inhalation Equipment); Hospital Noncritical Items (Bedpans/Furniture); Hospitals/Medical Institutions Premises (Human/Veterinary) non-conductive floors and noncritical premises; Reverse osmosis water systems.

#### INDOOR RESIDENTIAL:

Bathroom Premises/Hard Surfaces

#### PESTS:

##### Bacteria:

*Mycobacterium tuberculosis* and non-tuberculous mycobacteria, Spore-forming bacteria, *Pseudomonas* spp., *Salmonella* spp., *Streptococcus* spp., Bacterial spores, *Streptococcus pyogenes*, *Streptococcus faecalis*, *Streptococcus salivarius*, *Corynebacterium diphtheriae*, *Salmonella choleraesuis*, *Salmonella paratyphi*, *Salmonella schottmuelleri*, *Neisseria elongata*, *Acinetobacter calcoaceticus*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Pseudomonas cepacia*, *Klebsiella pneumoniae*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus aureus* (Penicillin Resistant), *Listeria monocytogenes*, *Salmonella typhimurium*, *Pediococcus damnosus*, *Lactobacillus buchneri*.

##### Fungi:

*Trichophyton mentagrophytes*, *Candida albicans*, *Aspergillus niger*, *Saccharomyces cerevisiae*.

##### Viruses:

Herpes simplex virus, Influenza A<sub>2</sub> virus, Human immunodeficiency virus type 1 (HIV-1), Hepatitis B virus.

**FORMULATION TYPES REGISTERED:**

TYPE: End Use

FORM: Liquid - Ready to Use, Soluble Concentrate/Liquid

**METHODS AND RATES OF APPLICATION:****TYPES OF TREATMENT:**

Sterilant/disinfectant for dialyzers and dialysis equipment, Percutaneous Transluminal Coronary Angioplasty catheters, anesthesia equipment, aseptic packaging and related surfaces in food processing plants, respiratory equipment, endoscopes, endotracheal tubes, dental hand instruments and burs, and surgical instruments - dialyzer treatment, angioplasty catheter treatment, immersion - 2000 to 50727 ppm a.i. by volume, 8000 to 60000 ppm a.i. by weight (sterilization); 160 to 2000 ppm a.i. by volume, 8000 to 60000 ppm a.i. by weight (disinfection).

Disinfectant for reverse osmosis membranes and their associated distribution systems (water related surface systems) - 2000 ppm a.i. by volume.

Disinfectant for hospital noncritical items made of plastic and stainless steel - immersion, mop, spray - 160 to 2000 ppm a.i. by volume, 8000 ppm a.i. by weight.

Used as a disinfectant for hard non-food contact surfaces such as floors, counter surfaces, machine exteriors, and premises in hospitals and medical, surgical, and dental offices and clinics, and laboratories; disinfectant/sanitizer for restrooms, pharmaceutical manufacturers, medical product manufacturers, electrical utility companies, semiconductor manufacturers, cosmetic manufacturers, and biotech companies - surface treatment, mop, brush-on, scrub, soak, sponge-on, spray, wipe-on - 755 to 6250 ppm a.i. by volume, 8000 ppm a.i. by weight (disinfection); 160 to 6250 ppm a.i. by volume (sanitation).

Used as a sanitizer of food-contact and non-food contact surfaces and equipment in dairies, breweries, wineries, and beverage plants - immersion, closed circulation system treatment, circulation method, premise treatment, spray - 118 ppm a.i. by volume (non-food use); 472 to 849 ppm a.i. by volume (food use).

Used as a disinfectant of food-contact and non-food contact surfaces and equipment in eating areas, dairies, breweries, wineries, and beverage plants - spray, mop, sponge-on, soak, scrub, wipe-on, brush-on - 755 ppm a.i. by volume.

Disinfection of animal life science laboratories, livestock premises, dairy cattle and goat

premises, poultry premises, trucks, coops, and crates - premise treatment, transportation vehicle treatment, feeding and watering appliance treatment - 755 ppm a.i. by volume.

Disinfection/sanitation of farm buildings and premises - brush-on, mop, premise treatment, sponge-on, spray, soak, scrub, wipe-on - 755 ppm a.i. by volume (disinfection); 118 ppm by volume (sanitation, non-food use).

**EQUIPMENT:**

Mop, sponge, brush, sprayer, mechanical sprayer, power sprayer, pump spray bottle, cloth, heated sterilizing tray, heating bath, automatic decontamination machine, and not specified.

**TIMING:**

Not Specified.

**RATE OF APPLICATION:**

See TYPES OF TREATMENT.

**USE PRACTICES LIMITATIONS:**

Only a fresh solution should be used when employed as a tuberculocide, cleaner, sanitizer, or hospital disinfectant (use-diluted). Re-use as a sterilant and broad system disinfectant (undiluted) for 30 days. Those used exclusively as sterilants for dialyzer reprocessing systems may be used undiluted for seven days. Do not allow products to mix with alkaline substances such as bleach or other oxidizing agents. Use AAMI [Association for the Advancement of Medical Instrumentation] Quality Water for Hemodialysis in making dilutions. Reuse of diluted products is not recommended. Do not store instruments to be sterilized in solution for more than 16 hours. Maintain temperature below 75 degrees Fahrenheit. Avoid contact with combustible materials. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas, and high pressures. Store product in original closed container-never tamper with the vent. The material of construction in some kidney machine parts may not be compatible with the product. Do not use rubber hoses to dispense product. The reverse osmosis membrane manufacturer should be consulted prior to use of some products to determine compatibility of the specific membranes.

Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been

absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent.

**FOR PEROXYACETIC ACID:**

**TYPE OF PESTICIDE:**

Tuberculocide, Sterilizer, Disinfectant (Bactericide/ Germicide, General or Broad-Spectrum, Hospital or Medical), Sanitizer, Virucide, Fungicide/Fungistat.

**USE SITES:**

**INDOOR FOOD:**

Agricultural/farm premises, buildings and equipment; Dairies/cheese processing plant equipment (food contact) and premises (nonfood contact); Livestock including poultry, dairy cattle and goats; (lactating or unspecified); Dairy farm milk handling facilities/equipment; Eating establishment equipment/utensils, food handling and serving areas (Food Contact); Food dispensing equipment/Vending machines; Food marketing/storage/distribution equipment/utensils (Food Contact); Food processing plant equipment (food contact) and plant premises (Nonfood Contact).

**INDOOR NON-FOOD:**

Animals (Laboratory/Research); Commercial/Institutional/Industrial floors, premises and Equipment; Eating Establishment Food Handling, Food Serving and Non-Food areas; Reverse osmosis water systems.

**INDOOR MEDICAL:**

Hospital/Medical Institution Premises (Human/Veterinary); Hospital/Medical Institution Noncritical Premises; Hospital Critical Items (Surgical Instruments/Pacemakers); Hospital Semicritical Items (Catheters/Inhalation equipment); Hospital Noncritical Items (Bedpans/Furniture); Hospital/Medical Institutions Non-conductive Floors; Reverse Osmosis Water Systems

**INDOOR RESIDENTIAL:**

Bathroom Premises/Hard Surfaces

**PESTS:****Bacteria:**

*Mycobacterium tuberculosis* and non-tuberculous mycobacteria, Spore-forming bacteria, *Pseudomonas spp.*, *Salmonella spp.*, *Streptococcus spp.*, Bacterial spores, *Streptococcus pyogenes*, *Streptococcus faecalis*, *Streptococcus salivarius*, *Corynebacterium diphtheriae*, *Salmonella choleraesuis*, *Salmonella paratyphi*, *Salmonella schottmuelleri*, *Neisseria elongata*, *Acinetobacter calcoaceticus*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Pseudomonas cepacia*, *Klebsiella pneumoniae*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus aureus* (Penicillin Resistant), *Listeria monocytogenes*, *Salmonella typhimurium*, *Pediococcus damnosus*, *Lactobacillus buchneri*.

**Fungi:**

*Trichophyton mentagrophytes*, *Candida albicans*, *Aspergillus niger*, *Saccharomyces cerevisiae*.

**Viruses:**

*Herpes simplex virus*, *Influenza A<sub>2</sub> virus*, Human immunodeficiency virus type 1 (HIV-1), Hepatitis B virus.

**FORMULATION TYPES REGISTERED:**

**TYPE:** End use.

**FORM:** Soluble concentrate/Liquid, Liquid-Ready to Use.

**METHODS AND RATES OF APPLICATION:****TYPES OF TREATMENT:**

Sterilant/disinfectant for dialyzers and dialysis equipment, Percutaneous Transluminal Coronary Angioplasty catheters, anesthesia equipment, aseptic packaging and related surfaces in food processing plants, respiratory equipment, endoscopes, endotracheal tubes, dental hand instruments and burs, and surgical instruments - dialyzer treatment, angioplasty catheter treatment, immersion - 400 to 8454 ppm a.i. by volume, 600 to 8500 ppm a.i. by weight (sterilization); 12 to 400 ppm a.i. by volume, 600 to 8500 ppm a.i. by weight (disinfection).

Disinfectant for reverse osmosis membranes and their associated distribution systems (water related surface treatment) - 400 ppm a.i. by volume.

Disinfectant for hospital noncritical items made of plastic and stainless steel - immersion, mop,

spray - 12 ppm to 600 ppm a.i. by volume, 600 ppm a.i. by weight.

Used as a disinfectant for hard non-food contact surfaces such as floors, counter surfaces, machine exteriors, and premises in hospitals and medical, surgical, and dental offices and clinics, and laboratories; disinfectant/ sanitizer for restrooms, pharmaceutical manufacturers, medical product manufacturers, electrical utility companies, semiconductor manufacturers, cosmetic manufacturers, and biotech companies - surface treatment, mop, brush-on, scrub, soak, sponge-on, spray, wipe-on - 100 to 400 ppm a.i. by volume, 600 ppm a.i. by weight (disinfection); 12 to 1250 ppm a.i. by volume (sanitation).

Used as a sanitizer of food-contact and non-food contact surfaces and equipment in dairies, breweries, wineries, and beverage plants - immersion, closed circulation system treatment, circulation method, premise treatment, spray - 26 ppm a.i. by volume (non-food use); 103 to 185 ppm a.i. by volume (food use).

Used as a disinfectant of food-contact and non-food contact surfaces and equipment in eating areas, dairies, breweries, wineries, and beverage plants - spray, mop, sponge-on, soak, scrub, wipe-on, brush-on - 164 ppm a.i. by volume.

Disinfection of animal life science laboratories, livestock premises, dairy cattle and goat premises, poultry premises, trucks, coops, and crates - premise treatment, transportation vehicle treatment, feeding and watering appliance treatment - 164 ppm a.i. by volume.

Disinfection/sanitation of farm buildings and premises - brush-on, mop, premise treatment, sponge-on, spray, soak, scrub, wipe-on - 164 ppm a.i. by volume (disinfection); 26 ppm by volume (sanitation, non-food use).

#### EQUIPMENT:

Cloth, mop, sponge, pump spray bottle, mechanical sprayer, power sprayer, brush.

#### TIMING:

Not Specified.

#### RATE OF APPLICATION:

See TYPES OF TREATMENT.

#### USE PRACTICE LIMITATIONS:

Only a fresh solution should be used when employed as a tuberculocide, cleaner, sanitizer, or hospital disinfectant (use-diluted). Re-use as a sterilant and broad system

disinfectant (undiluted) for 30 days. Those used exclusively as sterilants for dialyzer reprocessing systems may be used undiluted for seven days. Do not allow products to mix with alkaline substances such as bleach or other oxidizing agents. Use AAMI [Association for the Advancement of Medical Instrumentation] Quality Water for Hemodialysis in making dilutions. Reuse of diluted products is not recommended. Maintain temperature below 75 degrees Fahrenheit. Do not store instruments to be sterilized in solution for more than 16 hours. Avoid contact with combustible materials. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas, and high pressures. Store product in original closed container-never tamper with the vent. The material of construction in some kidney machine parts may not be compatible with the product. Do not use rubber hoses to dispense product. The reverse osmosis membrane manufacturer should be consulted prior to use of some products to determine compatibility of the specific membranes.

Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.

#### **FOR POTASSIUM PEROXYMONOSULFATE SULFATE:**

##### **TYPE OF PESTICIDE:**

This active ingredient is used only in conjunction with sodium chloride. Peroxymonosulfate sulfate oxidizes sodium chloride to hypochlorous acid.

Air sanitizer, broad spectrum disinfectant for industrial animal and agricultural facilities, fungicide (mold/mildew), virucide

##### **USE SITES:**

###### **INDOOR FOOD:**

Poultry (Egg/Meat)

Poultry Processing Plant Premises (Nonfood Contact)

###### **INDOOR NON-FOOD:**

Egg Handling Equipment (Hatching)

Egg Handling Rooms (Hatching)

**INDOOR RESIDENTIAL:**  
Air Treatments (Commercial/Household)

**PESTS:**

Bacteria:

*Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum*

Fungi:

*Aspergillus flavus, Aspergillus fumigatus, Candida albicans*

Viruses:

Newcastle Disease Virus, Infectious Bronchitis Virus, Infectious Bursal Disease Virus, Avian Laryngotracheitis Virus, Avian Influenza Virus and Marek's Disease Virus

**FORMULATION TYPES REGISTERED:**

TYPE: End use

FORM: Solid soluble concentrate

**METHODS AND RATES OF APPLICATION:**

TYPES OF TREATMENT: Surface treatment, Spray, Fog, Feeding and watering appliance treatment

EQUIPMENT: Fogger, Sprayer

TIMING: Not specified

**RATE OF APPLICATION:**

Indoor food:

From 1,987 up to 4,128 ppm of active ingredient by weight

Indoor non-food:

From 1,987 up to 4,128 ppm of active ingredient by weight

Indoor residential:

From 1,987 up to 4,128 ppm of active ingredient by weight

**USE PRACTICES LIMITATIONS:**

Remove animals and feed from premises before treatment.

### **C. Data Requirements**

The Agency imposed the target data requirements for reregistration on the three active ingredients for their currently registered uses. These target data requirements included Technical Chemistry, Toxicology, and Environmental Fate and Ecological Effects. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

### **D. Regulatory History**

Hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate products were registered in the United States as early as 1977, 1985, and 1968 respectively as disinfectants, sanitizers and sterilants. Currently, 23 products are registered for use in/on agricultural premises, food establishments, commercial/industrial locations and hospital/medical institutions on a variety of hard surfaces such as equipment, floors and walls in indoor and outdoor applications.

Historically, certain hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate products and certain other liquid chemical germicides have been regulated both as pesticides and as devices. In an effort to resolve the confusion and burden of dual regulation, a Memorandum of Understanding (MOU) was signed on June 4, 1993 between EPA and the Food and Drug Administration (FDA). The objectives of the MOU are to (1) stimulate both Agencies to undertake rulemaking to permanently vest exclusive jurisdiction for certain categories of chemical germicides in each Agency and (2) serve as interim guidance designed to minimize duplicative regulatory requirements between the two Agencies until the rulemaking is complete.

The MOU separates the liquid chemical germicides into the following two categories based on their use patterns and efficacy claims: (1) sterilants and (2) general purpose disinfectants. Sterilants, under this agreement, refer to those chemical germicides used to reprocess reusable critical and semicritical devices as defined by the Centers for Disease Control (CDC). Critical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. Semicritical devices are those which contact intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. General disinfectants are defined as all remaining types of public health liquid chemical germicides bearing non-sterilant claims for use on non-critical surfaces.

The MOU outlines the future separate regulation of liquid chemical germicides as either pesticides under FIFRA or devices under FFDCA by granting each Agency primary jurisdiction over one of the two categories. All products which bear sterilant label claims and can be used on critical or semicritical surfaces will be regulated by FDA as devices. In addition, many sterilant products have claims which correspond to a high level disinfectant use pattern. These

claims will also be regulated by FDA for the sterilant products. EPA will regulate the general purpose disinfectants.

Because the MOU does not change the statutory authority granted under FIFRA and FFDCA, both Agencies will continue to have jurisdiction over all liquid chemical germicides and will continue registration and premarket approval until rulemaking has been completed. However, the MOU reduces the regulatory burden by stating that the required data to support efficacy claims and product performance need only be submitted and reviewed by the Agency with primary jurisdiction as defined above. In the case of these peroxy compound products, EPA has primary jurisdiction and the conditions of reregistration must be fulfilled and required data submitted as presented in Appendices F and G.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

##### Hydrogen Peroxide

Hydrogen peroxide is a colorless, slightly pungent liquid with a density of 1.438 at 20°C. It is infinitely soluble in water. It is an unstable corrosive liquid with strong oxidizing characteristics. This product is marketed generally at 3.1 to 35.0% aqueous solution.

##### Peroxyacetic acid

Peroxyacetic acid is a colorless liquid. At low concentrations it is odorless, but has a strong pungent odor when present at 40% or higher concentration. It boils at 103°C, probably with decomposition. It is a non-flammable, strong oxidizing, unstable compound with a pH of 2 to 3. It has a density of 1.13.

##### Potassium peroxymonosulfate sulfate

Potassium peroxymonosulfate sulfate is an odorless white granular powder with a density of 1.12 - 1.20 g/cm<sup>3</sup>. It melts at 235°C and it decomposes before boiling. It is a stable, non-flammable chemical with strong oxidizing characteristics. It is 25.6% soluble in water at room temperature. The pH of this chemical is 2.3 for a 1% aqueous solution. In the one registered product, it occurs as a triple salt, i.e., potassium peroxymonosulfate sulfate. Potassium peroxymonosulfate sulfate is registered only for uses in conjunction with sodium chloride ions in water to produce hypochlorous acid.

## B. Human Health Assessment

### 1. Toxicology Assessment

The acute toxicological data for hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate are summarized below. The data available to the Agency are adequate and will support reregistration eligibility of these compounds.

#### a. Acute Toxicity

Table I: Acute Toxicity - Hydrogen Peroxide

Test	Result*	Category
Acute Oral LD <sub>50</sub> (mouse)	2000 mg/kg	III
Acute Dermal LD <sub>50</sub> (rat)	4060 mg/kg	III
Acute Inhalation LC <sub>LO</sub> (mouse)	227 ul/L	II
Eye Irritation (rabbit)	severe irritation	I
Dermal Irritation (rabbit)	corrosive	I
Skin Sensitization	-	-

\* SAX, Irving N. and Lewis, Richard J., "Dangerous Properties of Industrial Materials" Seventh edition, Van Nostrand Reinhold, 1989, H1B000.

**Table II:** Acute Toxicity - Peroxyacetic acid

Test	Result*	Category
Acute Oral LD <sub>50</sub> (rat)	1540 mg/kg	III
Acute Dermal LD <sub>50</sub> (rabbit)	1410 mg/kg	II
Acute Inhalation LC <sub>50</sub> (rat)	0.450 mg/L	II
Eye Irritation (rabbit)	severe irritation	I
Dermal Irritation (rabbit)	corrosive	I
Skin Sensitization	-	-

\* SAX, Irving N. and Lewis, Richard J., "Dangerous Properties of Industrial Materials" Seventh edition, Van Nostrand Reinhold, 1989, PCL500.

**Table III:** Acute Toxicity - Potassium Peroxymonosulfate Sulfate

Test	Result	Category
Acute Oral LD <sub>50</sub> (rat) <sup>1</sup>	1287 mg/kg (♀) 1129 mg/kg (♂)	III
Acute Dermal LD <sub>50</sub> (rat) <sup>2</sup>	> 2000 mg/kg	III
Acute Inhalation LC <sub>50</sub> (rat) <sup>3</sup>	> 5.0 mg/L	IV
Eye Irritation (rabbit) <sup>4</sup>	severe corneal opacity	I
Dermal Irritation (rabbit) <sup>5</sup>	corrosive	I
Skin Sensitization (guinea pig) <sup>6</sup>	negative	n/a <sup>7</sup>

<sup>1</sup> 81-1, MRID 426074-01

<sup>2</sup> 81-2; MRID 426074-02

<sup>3</sup> 81-3; MRID 425912-01

<sup>4</sup> 81-4; MRID 426074-03

<sup>5</sup> 81-5, MRID 426074-04

<sup>6</sup> 81-6, MRID 426074-05

<sup>7</sup> n/a = not applicable

Hydrogen peroxide, peroxyacetic acid, and potassium peroxymonosulfate

sulfate are oxidizing agents; in general, the organic peroxides are stronger oxidants than hydrogen peroxide. It is well known that peroxides react (sometimes violently) with materials containing reducing agents, and concentrated materials are routinely handled with care because of the potential for strong chemical reactions. The high reactivity of the peroxides are evident from the acute effects observed from exposure to these compounds by the dermal or ocular routes. They are corrosive and severely irritating to the eyes, skin and mucous membranes (Toxicity Category I). In contrast, exposure by the oral route appears to be moderately acutely toxic (Toxicity Category III). Therefore, specifically because of these very reactive properties and moderately low oral toxicity, dilute concentrations of peroxides have found wide applications as disinfectants.

**b. Other Toxic Endpoints**

Based on the chemical reactivity of peroxides, these compounds would be expected to have biological activity, particularly with macromolecules. Hydrogen peroxide, for example, is a known mutagenic compound with activity in such assays as the *Salmonella* assay (Ames test), aberrations and sister chromatid exchanges in cultured mammalian cells, and for DNA damage and repair in cultured human fibroblasts.

**2. Exposure Assessment**

**a. Dietary Exposure**

Hydrogen peroxide and peroxyacetic acid are used in dairy/cheese processing plants, on food processing equipment and in pasteurizers in breweries, wineries, and beverage plants. Although some contact may occur between treated equipment and food, no residues are expected since only trace amounts would come in contact with food having contacted treated equipment and both compounds degrade rapidly (in air) primarily to oxygen and water or oxygen and acetic acid. In addition, both of these compounds are generally recognized as safe (GRAS) according to the Food and Drug Administration (21 CFR §178.1010 Sanitizing solutions) when used on food-processing equipment, utensils, and other food-contact articles. Dietary exposure is possible; however, these chemicals react instantly upon contact with materials such as food and are degraded to moieties which present no toxicological concern.

Potassium peroxymonosulfate sulfate as a disinfectant is used in poultry houses, hatcheries and processing plants. These uses involve removal of the animals or meat/eggs before use, followed by a potable water rinse and time for

drying before re-introducing the poultry. In processing houses, the uses are limited to floors, ceilings, and walls. This active ingredient is not used directly on poultry/meat. This is considered a non-food use and no dietary exposure is expected to occur as a result of pesticidal/disinfectant uses.

**b. Occupational and Residential**

Hydrogen peroxide and peroxyacetic acid, in the form of a soluble concentrate/liquid, are used for industrial/commercial floors, medical equipment, e.g., dialysis parts, catheters, surfaces, furniture, equipment, etc; and residential bathroom surfaces. It is also used in dairy/cheese processing plants on food processing equipment and in pasteurizers in breweries, wineries, and beverage plants. Applications are primarily by immersion, mop, sponging or wipe-on, and spraying (dilutes, 1% or less). There is a potential for applicator/mixer exposure. Considering these compounds are corrosive and severely irritating to the skin, eyes and mucous membranes (Toxicology Category I), exposure is a concern. Protective equipment is required on the labels including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thoroughly washing with soap and water after handling (including clothing) is recommended. The use of protective equipment sufficiently minimizes the exposure to applicators/mixers for these uses including the spray applications which are 1% concentration or less.

Potassium peroxyomonosulfate sulfate in the form of a soluble concentrate/liquid is used in conjunction with sodium chloride to produce hypochlorous acid. Hypochlorous acid is a strong oxidizing agent; it is this oxidizing effect which imparts the disinfection/sanitation properties. The soluble concentrate/solid is diluted for spraying/misting/fogging poultry houses, hatcheries and processing plants. Based on these uses dermal and inhalation exposure to applicators/mixers is expected. Considering this chemical is corrosive and causes severe eye, skin and mucous membrane irritation (Toxicology Category I) protective equipment is required on the labels including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thoroughly washing with soap and water after handling (including clothing) is recommended. Through the use of protective equipment, exposure to applicators/mixers is minimized.

There is a potential for post-application exposure; however, based on the current uses, exposure is expected to be minimal.

**3. Risk Assessment**

The Agency has a concern for an acute risk based on Toxicology Category I for

skin and eye irritation. The acute risk from occupational exposure to these three corrosive compounds is minimized through the use of protective equipment. There is essentially no dietary exposure to these compounds based on these uses and their quick degradation; therefore, no significant risk is associated with dietary or chronic exposure. Based on these factors and the pesticidal use patterns, the human risks are considered to be negligible. No additional hazard or exposure data are required for reregistration eligibility for these compounds.

## C. Environmental Assessment

### 1. Environmental Fate Assessment

#### a. Chemical Fate.

Peroxy compounds are highly reactive and short-lived because of the inherent instability of the peroxide bond (O-O bond). Instead of the usual oxygen oxidation number of -2, peroxide oxygen atoms have an oxidation number of -1 due to the presence of two additional electrons. The peroxide bond is weak, and breaking it to form water and O<sub>2</sub> is so highly favored thermodynamically that improperly stored quantities of highly concentrated peroxides may explode. A more positive aspect of this instability, however, is that at typical pesticidal concentrations, peroxides are not explosive, but do degrade rapidly.

Hydrogen peroxide is a strong oxidizing agent in both acidic and basic solutions, but the reduction potentials (E°) vary as a function of pH. Oxidation with hydrogen peroxide in acidic solutions is slow, but it is rapid in basic solutions. Hydrogen peroxide also behaves as a reducing agent (both in acidic and basic solutions) when it reacts with stronger oxidizing agents, such as with permanganate ions in an acidic solution. Therefore, many redox systems and metal surfaces can serve as catalysts for peroxide decomposition. The degradates of hydrogen peroxide are water and oxygen.

Peroxyacetic acid is produced by the interaction of hydrogen peroxide and acetic acid. Peroxyacetic acid is an oxidizing agent, although it can act indirectly by decomposing to acetic acid and releasing a hydrogen peroxide molecule. Peroxyacetic acid can also provide a source of free radicals, which can attack C-H bonds in target molecules (e.g., the C-H bonds in a microbial cell membrane). The primary degradates of peroxyacetic acid are acetic acid, water and oxygen. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.

Potassium peroxymonosulfate sulfate is registered for use in conjunction

with sodium chloride (NaCl). The reaction of peroxymonosulfate sulfate with chloride anions generates hypochlorous acid, which is a well-known oxidizing agent. Both the oxidation reaction of peroxymonosulfate with chloride anions and the speciation of hypochlorous acid (which is a weak acid) are affected by the pH of the aqueous medium. In addition, the rate and mechanism of decomposition of hypochlorous acid are also dependent on temperature, concentration and exposure to sunlight.

Because pH affect both the reaction of peroxymonosulfate sulfate with chloride anions and the speciation of hypochlorous acid, it is recommended that the pH of the dilution water used with this product(s) be specified on the label(s) for optimum and safe use of the product. The optimum sanitation potential and safe use of the product occurs in the pH range of 7.2 to 7.6.

**b. Environmental Fate.**

Hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate (in conjunction with sodium chloride) are registered exclusively for indoor use, with no direct exposure to the environment when used according to the directions on the label.

**2. Ecological Effects**

The following four studies would normally be required for labeling purposes concerning non-target species:

- 71-1(a) Acute Avian Oral, Quail/Duck
- 71-2(b) Acute Avian Dietary Duck
- 72-1(c) Acute Fish Toxicity Rainbow Trout
- 72-2(a) Acute Aquatic Invertebrate Toxicity

**a. Hydrogen Peroxide and Peroxyacetic Acid**

For hydrogen peroxide and peroxyacetic acid, the two avian studies were waived because of their indoor use pattern and the corrosive nature of these chemicals. These chemicals are considered highly toxic on an acute basis.

The two aquatic studies were waived for hydrogen peroxide and peroxyacetic acid because of the indoor use pattern and because these chemicals readily degrade to oxygen or carbon dioxide and water.

b. **Potassium Peroxymonosulfate Sulfate**

The acute avian oral study was waived for potassium peroxyomonosulfate sulfate because of its corrosive nature. This chemical is considered highly toxic on an avian oral acute basis.

Avian dietary studies for the bobwhite quail (MRID No. 204057) and the mallard duck (MRID No. 204058) were submitted to the Agency. A preliminary review of the studies indicates that these studies will fulfill the guideline requirements for potassium peroxyomonosulfate sulfate. The studies indicate an LC50 > 5000 ppm for these species of birds. The chemical is classified as practically non-toxic to birds on a dietary basis.

Acute fish toxicity studies (MRID No.19852) using potassium peroxyomonosulfate sulfate as the test material and rainbow trout and bluegill sunfish as the test species were submitted to the Agency. A review of the studies indicates that these studies will fulfill the guideline requirements. The LC50 for rainbow trout was 0.78 mg/l classifying the chemical as highly toxic. The LC50 for the bluegill sunfish was 1.0 mg/l classifying it as moderately toxic. The acute aquatic invertebrate study was waived because of the indoor use pattern and the high toxicity to aquatic organisms as indicated by the rainbow trout study.

All of the use patterns for the three chemicals are considered indoor because of the potential for high volume use. A National Pollutant Discharge Elimination System (NPDES) permit for products which are sold for industrial or commercial use may be required.

#### **IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

##### **D. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate sulfate active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing one or more of these active ingredients. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of these chemicals and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the

registered uses of hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate and to determine that they can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing any one of these active ingredients, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

### **1. Eligibility Decision**

Based on the reviews of the generic data for hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate, the Agency has sufficient information to determine whether these chemicals will cause unreasonable adverse effects to humans or the environment. The Agency concludes that products containing hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate for all uses are eligible for reregistration and as labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

### **2. Eligible and Ineligible Uses**

The Agency has determined that all uses of Hydrogen peroxide, peroxyacetic acid and potassium peroxymonosulfate sulfate are eligible for reregistration.

### **E. Regulatory Position**

In consideration of the above information about hydrogen peroxide, peroxyacetic acid, and potassium peroxymonosulfate sulfate, the Agency finds no reason to impose new risk reduction measures for currently registered uses. The Agency will however, assess the need for product specific risk reduction measures upon receipt of data that are being required under the Product Specific Data Call-in Notice appended to this document. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

## **IV. ACTIONS REQUIRED BY REGISTRANTS**

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

### **A. Manufacturing-Use Products**

#### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of Hydrogen peroxide, Peroxyacetic acid and Potassium peroxyomonosulfate sulfate for the above eligible uses has been reviewed and determined to be substantially complete.

#### **2. Labeling**

All manufacturing-use products containing any of these three active ingredients pesticides must have the following Environmental Hazard Statement on their labels:

"this pesticide is toxic to birds, fish and aquatic invertebrates."

The following is required labeling for all manufacturing-use products:

"Do not discharge effluent containing these products into lakes, streams, ponds, estuaries, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing these products to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional office of the U.S. Environmental Protection Agency."

### **B. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix F, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment 5) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current

testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

## **2. Labeling Requirements for End-Use Products**

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10.

The following label statement is required for all end-use products containing potassium peroxyomonosulfate sulfate:

"Because pH may affect both the redox potential of the reaction and the speciation of the weak hypochlorous acid reaction product, the pH of the dilution water must be specified on the labels of products containing potassium peroxyomonosulfate sulfate and sodium chloride salts. The optimum sanitation potential and safe use of the product occurs in the pH range of 7.2 to 7.6."

The following label statement is required for all end use products containing the active ingredient potassium peroxyomonosulfate sulfate, hydrogen peroxide or peroxyacetic acid:

For end use products having an indoor residential or medical (veterinary) use pattern, the following environmental hazard statement should appear on the label:

"This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk."

### **Precautionary Labeling**

For end-use products for industrial and commercial uses:

All end-use product labels for commercial/industrial uses and medical uses must include protective equipment including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thorough washing with soap and water after handling (including clothing) should also be recommended. These label requirements should appear as appropriate based on the end-use product toxicity.

For products which may have industrial/commercial applications:

"Do not discharge effluent containing these products into lakes, streams, ponds, estuaries, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing

these products to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional office of the U.S. Environmental Protection Agency."

#### C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED.

## **V. APPENDICES**



## **APPENDIX A. Table of Use Patterns Subject to Reregistration**







**SITE Application Type, Application**

Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)

**APPENDIX A - CASE 4072, [Peroxy compsl Chemical 000595 (Hydrogen peroxide)]**

Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Use
Application Rate	Application Rates	Text	Apps @ Max Dose	crop cycle, or /year	Interval (days)	Entry Interval (days)	Allowed	Disallowed	Limitations Codes
SC/L V 755	V 755 *	NS		NS NS	NS		A0B, A13, A30, A10(10), A29(500)		
SC/L V 755	V 755 *	NS		NS NS	NS		A0B, A13, A30, A10(10), A29(500)		

**USES ELIGIBLE FOR REREGISTRATION****FOOD/FEED USES (con't)****DAIRY CATTLE (LACTATING OR UNSPECIFIED) (con't)**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY FARM MILK HANDLING FACILITIES/EQUIPMENT**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**DAIRY FARM MILKING EQUIPMENT**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**DAIRY GOATS (LACTATING OR UNSPECIFIED)**

Premise treatment., Not on Label., Brush., Hard., Organic soil (5%).

Premise treatment., Not on Label., Cloth., Hard., Organic soil (5%).

Premise treatment., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).

Premise treatment., Not on Label., HDP., Hard., Organic soil (5%).

Premise treatment., Not on Label., Not on Label., Hard., Organic soil (5%).

**FOOD (con't)****Use Group: INDOOR FOOD (con't)**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY HORSES**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**DAIRY PIGS**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**DAIRY SHEEP**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**DAIRY SWINE**

Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

Spray., Not on Label., Sprayer., Hard., Not applicable for this use.

**FOOD (con't)****Use Group: INDOOR FOOD**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY CATTLE (LACTATING OR UNSPECIFIED)**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY HORSES**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY SHEEP**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**DAIRY SWINE**

Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%),

Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%),

**SITE Application Type, Application**

Timing, Application Equipment -  
Surface Type & Efficacy Influenc-  
ing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION****FOOD/FEE USES (con't)**

	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Graphic	Use
<b>DAIRY EQUIPMENT (CLASIFYING OR UNSPECIFIED) (con't)</b>											
Premise treatment., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Premise treatment., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
<b>EATING ESTABLISHMENTS EQUIPMENT/UTENSILS (FOOD CONTACT)</b>											
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., SC/L V 755	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., SC/L V 755	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
<b>EATING ESTABLISHMENTS FOOD HANDLING AREAS (FOOD CONTACT)</b>											
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., SC/L V 755	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., SC/L V 755	SC/L	V 755			V 755	*	NS		NS NS	NS	A08, A13, A30, A10(10), A29(500)

SITE Application Type, Application  
Timing, Application Equipment –  
Surface Type & Efficacy Influenc-  
ing Factor (Antimicrobial only)

Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Graphic	Use
Application Rate		Application Rates (Max & Max Dose)	Text Apps Rate	crop cycle, or /year	Interval (days)	Interval (days)				Disallowed
										Limitations Codes

**USES ELIGIBLE FOR REREGISTRATION****FOOD/FEED USES (con't)****EATING ESTABLISHMENTS: FOOD HANDLING AREAS (FOOD CONTACT) (con't)**

Use Group: INDOOR FOOD (con't)										
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

**EATING ESTABLISHMENTS: FOOD SERVING AREAS (FOOD CONTACT)**

Use Group: INDOOR FOOD										
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on Label., Not on Label., Hard., SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

**FOOD DISPENSING EQUIPMENT/VENDING MACHINES**

Use Group: INDOOR FOOD										
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)



## SITE Application Type, Application

Timing, Application Equipment – Surface Type & Efficacy Influencing factor (Antimicrobial only)

## USES ELIGIBLE FOR REREGISTRATION

## FOOD/FEE USES (con't)

## FOOD PROCESSING PLANT EQUIPMENT (FOOD CONTACT)

	Form Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Use
	Application Rate	Application Rates	(Max Dose)	Text Rate	/crop cycle, or /year	Interv (days)	Entry Interv (days)	Disallowed
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A08, A10(10), A29(500)
Circulation method., Not on label., Not on label., Hard., Not applicable for this use.	SC/L V 472	V 849	*	NS	NS	NS	NS	A08, A13, A30, A08, A25(2), A29(500)
Closed circulation system treatment., Not on label., Hard., A33(5), Not on label., Hard., Not applicable for this use.	SC/L V 543	V 644	*	NS	NS	NS	NS	A08, A25(1), A34(40)
Immersion., Not on label., Not on label., Hard., Not applicable for this use.	SC/L V 472	V 849	*	NS	NS	NS	NS	A08, A13, A30, A08, A25(2), A29(500)
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Sprayer., Hard., Not applicable for this use.	SC/L V 472	V 849	*	NS	NS	NS	NS	A08, A13, A30, A08, A25(2), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

## FOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT)

	Form Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Use
	Application Rate	Application Rates	(Max Dose)	Text Rate	/crop cycle, or /year	Interv (days)	Entry Interv (days)	Disallowed
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A08, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L V 755	V 755	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Premise treatment., Not on label., Not on label., Hard., Not applicable for this use.	SC/L V 118	V 118	*	NS	NS	NS	NS	A08, A13, A30, A08, A25(5), A29(500)
Scrub., Not on label., Not on label., Hard., SC/L V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30,

**SITE Application Type, Application**

**Timing, Application Equipment -**  
Surface Type & Efficacy Influencing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION**  
**FOOD/FEED USES (con't.)**

**FOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT) (con't.)**

	Form	Minimum Application Rate	Max. Application Rates	Text	Maximum Dose	Min.	Restr.	Geographic	Graphic	Use
Soak., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

**LIVESTOCK**

	Use Group: INDOOR FOOD	Use Group: INDOOR FOOD (con't.)	Use Group: INDOOR FOOD	Use Group: INDOOR FOOD	Use Group: INDOOR FOOD
Premise treatment., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Premise treatment., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS

**PREMISE TREATMENT**

	Use Group: INDOOR FOOD				
Not on label., Hop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS
Feeding and watering appliance treatment., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS

SITE Application Type, Application Timing, Application Equipment Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use	Limitations Codes
Application Rate	Application Rates	Text	Apps /crop cycle, Max & Max Rate	Interv	Entry Allowed or year (days)	Entry (days)	Interv (days)	Disallowed		

SITE Application Type, Application	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Graphic	Use
Timing, Application Equipment -	Application Rate	Application Rates	Text	Apps @ Max Dose)	/crop cycle, or /year	Interval (days)	Entry Interval (days)	Allowed	Disallowed	Limitations	Codes
Surface Type & Efficacy Influencing Factor (Antimicrobial only)											

## USES ELIGIBLE FOR REREGISTRATION

## NON-FOOD/NON-FEED (con't)

APPENDIX A - CASE 4072, [Peroxy Compds] Chemical 000595 [Hydrogen peroxide]											
BATHROOM PREMISES/HARD SURFACES (con't)											
Scrub., Not on label., Not on label., Hard., SC/L V 755		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Soak., Not on label., Not on label., Hard., Organic soil (5%).		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Sponge-on., Not on label., Sponge., Hard., Not applicable for this use.		V 6250	*	NS			NS	NS	NS	A0B, A10(10), A06	
SC/L V 160		V 160	*	NS			NS	NS	NS	A0B, A10(5)	
Sponge-on., Not on label., Sponge., Hard., SC/L V 755		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.		W 8000	*	NS			NS	NS	NS	A0B, A10(0.5)	
SC/L V 2000		V 2000	*	NS			NS	NS	NS	A10(10)	
Wipe-on., Not on label., Cloth., Hard., Not applicable for this use.		SC/L V 6250	*	NS			NS	NS	NS	A0B, A10(10), A06	
SC/L V 160		V 160	*	NS			NS	NS	NS	A0B, A10(5)	
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).		SC/L V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
COMMERCIAL/INSTITUTIONAL/FLOORS											
Brush-on., Not on label., Brush., Hard., Organic soil (5%).		SC/L V 755	V 755	*	NS		NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Mop., Not on label., Mop., Hard., Not applicable for this use.		SC/L V 6250	V 6250	*	NS		NS	NS	NS	A0B, A10(10), A06	
Mop., Not on label., Mop., Hard., Organic soil (5%).		SC/L V 755	V 755	*	NS		NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Scrub., Not on label., Not on label., Hard., Organic soil (5%).		V 755	*	NS			NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	

APPENDIX A - CASE 4072, [Peroxyl products] Chemical 000595 [Hydrogen peroxide]							Page 11		
SITE Application Type, Application	Form	Minimum	Maximum	Soil Max.	Maximum Dose Min.	Restr. Geographic	Geographic	Use	Limitations Codes
Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Application Rate	Application	Text	Text	/crop cycle, @ Max or /year	Interval Allowed	Days	Days	Days

SITE Application Type, Application Form	Minimum	Maximum	Soil Max.	Max.	Maximum Dose	Min.	Restr. Geographic	Geographic	Use	Limitations Codes
Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Application Rate	Application Rates	Text	Max	Apps /crop cycle, or /year	Interv (days)	Entry Allowed	Geographic	Disabled	Geographic

IEEE STANDARDS

WOW - FOOD (NOW = FEED (soon))

COMMERCIAL/INSTITUTIONAL/PREMIUM EQUIP. (INDOOR)		Use Group: INDOOR NON-FOOD (cont'd)	
Spray-, Not on label -, Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Spray-, Not on label -, Power sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Spray-, Not on label -, Pump spray bottle., Hard., Not applicable for this use.	SC/L V 2000	V 2000 *	NS NS NS NS
Wipe-on-, Not on label -, Cloth., Hard., Not applicable for this use.	SC/L V 6250	V 6250 *	NS NS NS NS
Wipe-on-, Not on label -, Cloth., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
EATING ESTABLISHMENTS FOOD HANDLING AREAS (NONFOOD CONTACT)		Use Group: INDOOR NON-FOOD	
Brush-on-, Not on label -, Brush., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Mop-, Not on label -, Mop., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Scrub-, Not on label -, Not on label -, Hard., SC/L V 755 Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Soak-, Not on label -, Not on label -, Hard., SC/L V 755 Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Sponge-on-, Not on label -, Sponge., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Spray-, Not on label -, Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Spray-, Not on label -, Power sprayer., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
Wipe-on-, Not on label -, Cloth., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS
EATING ESTABLISHMENTS FOOD SERVING AREAS (NONFOOD CONTACT)		Use Group: INDOOR NON-FOOD	
Brush-on-, Not on label -, Brush., Hard., Organic soil (5%).	SC/L V 755	V 755 *	NS NS NS NS

SITE Application type, Application  
Timing, Application Equipment -  
Surface Type & Efficacy Influenc-  
cing Factor (Antimicrobial only)

## USES ELIGIBLE FOR REREGISTRATION

## NON-FOOD/NON-FEED (con't)

## EATING ESTABLISHMENTS FOOD SERVING AREAS (NONFOOD CONTACT) (con't)

	Form	Minimum Application Rate	Maximum Application Rates (Max Dse)	Soil Max. Rate	Text Apps & Max Dse	Maximum Dose	Min. Interv. or /year	Entry Allowed (days)	Restr. Geographic	Geographic	Use Disallowed	Limitations Codes	
Mop-, Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Scrub., Not on label., Not on label., Hard., SC/L Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Soak-, Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Spray., Not on label., Power sprayer., Hard., Organic soft (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
<b>EATING ESTABLISHMENTS NONFOOD AREAS (NONFOOD CONTACT)</b>													
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop-, Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., SC/L Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

**SITE Application Type, Application**

**Timing, Application Equipment –**  
Surface Type & Efficacy Influencing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION****NON-FOOD/NON-FEED (con't)****HOSPITAL CRITICAL ITEMS (SURGICAL INSTRUMENTS/PACEMAKERS)**

Angioplasty catheter treatment., Not on Label., Not Applicable., Not applicable for this use.

Dialyzer treatment., Not on Label., Not on Label., Not Applicable., Not applicable for this use.

Gas sterilization treatment., Not on Label., RTU Automatic decontamination machine., Hard., Not applicable for this use.

Immersion., Not on Label., Heated sterilizing tray., Hard., Not applicable for this use.

Immersion., Not on Label., Heating bath., Hard., Not applicable for this use.

Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.

RTU W 60000 RTU W 60000 RTU W 60000 RTU W 8000 SC/L W 8000 SC/L W 8000

SC/L V 160 SC/L V 42272 SC/L V 50727 RTU W 60000

SC/L V 2000 SC/L V 2000 SC/L V 2000 SC/L V 2000

SC/L V 2000 SC/L V 2000 SC/L V 2000 SC/L V 2000

**USES ELIGIBLE FOR REREGISTRATION**

**NON-FOOD/NON-FEED (con't)**

**USE GROUP: INDOR MEDICAL**

W 80000 \* NS

No Calc \* NS

V 2000 \* NS

V 2000 \* NS

V 42272 \* NS

V 50727 \* NS

W 60000 \* NS

W 60000 \* NS

W 60000 \* NS

W 8000 \* NS

**Geographic**

Interv Entry Allowed

or /year (days)

Interv (days)  
(days)

**Disallowed****Geographic****Limitations**

Codes

A08

A08, A10(10), A16

A08, A11(11), A16,

A12(75)

A08

A08, A10(10), A16,

A36(50)

A08

A08, A10(10), A16,

A36(20)

A08

A08, A10(10), A06,

A36(20)

A08, A11(5-5), A16,

A36(20)

A08

A08, A10(10), A06,

A36(20)

A08

A08, A10(10), A16,

A36(50)

A08

A08, A10(10), A16,

A36(50)

A08

A08, A10(10), A06,

A36(20)

A08

A08, A10(10), A06,

A36(20)

A08

A08, A10(10), A06,

A36(20)

A08, A10(10), A16

SITE Application Type, Application

SITE Application Type, Application

Timing, Application Equipment — Surface Type & Efficacy Influencing Factors (Antimicrobial analysis)

SOURCES OF VARIANCE FOR PREFERENCE

WON - FOOD (NON-FED) (CONT'D)

SITE Application type, Application  
Timing, Application Equipment ~  
Surface Type & Efficacy Influenc-  
ing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION****NON-FOOD/NON-FEED (con't)**

	Form	Minimum Application Rate	Maximum Application Rates (Max Dose)	Text Rate	Apps @ Max Dose	Maximum Dose	Min. Interv. cycle, or /year	Entry Allowed (days)	Geographic Area	Disallowed	Geographic	Use
<b>HOSPITAL/MEDICAL INSTITUTIONS NON CONDUCTIVE FLOORS</b>												
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 8000	W 8000	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(0.5)
	SC/L	V 2000	V 2000	*	NS	NS	NS	NS	NS	NS	NS	A10(10)
<b>HOSPITALS/MEDICAL INSTITUTIONS NONCRITICAL PREMISES</b>												
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	V 2000	V 2000	*	NS	NS	NS	NS	NS	NS	NS	A10(10), A06
<b>HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)</b>												
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 8000	W 8000	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(0.5)
	SC/L	V 2000	V 2000	*	NS	NS	NS	NS	NS	NS	NS	A10(10), A06
<b>Surface treatment., Not on label., Not on label., Hard., Not applicable for this use.</b>												
	SC/L	V 1000	V 1000	*	NS	NS	NS	NS	NS	NS	NS	A08
wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 755	V 755	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

**SITE Application Type, Application**

**Timing, Application Equipment -**  
Surface Type & Efficacy Influen-  
cing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION****NON-FOOD/NON-FEED (con't)**

SITE Application Type, Application	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Graphic	Disallowed	Geographic	Use	Limitations Codes
<b>REVERSE OSMOSIS WATER SYSTEM</b>														
Water related surface treatment, Not on label., Not on Label., Not Applicable., Not applicable for this use.	SC/L	V	2000		V	2000	*	NS		NS	NS	NS	NS	NS
Water treatment, Not on label., Not on Label., Not Applicable., Not applicable for this use.	SC/L	V	2000		V	2000	*	NS		NS	NS	NS	NS	NS
<b>INDOOR MEDICAL</b>														
Water related surface treatment, Not on label., Not on Label., Not Applicable., Not applicable for this use.	SC/L	V	2000		V	2000	*	NS		NS	NS	NS	NS	NS
Water treatment, Not on label., Not on Label., Not Applicable., Not applicable for this use.	SC/L	V	2000		V	2000	*	NS		NS	NS	NS	NS	NS

A0B, A10(10)  
A0B, A10(10)  
A0B, A10(10)

**LEGEND****HEADER ABBREVIATIONS**

Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate  
 Min. Interv (days) : Minimum Interval between Applications (days)  
 Restr. Entry Interv (days) : Restricted Entry Interval (days)

**SOIL TEXTURE FOR MAX APP. RATE**

- \* : Non-specific
- C : Coarse
- M : Medium
- F : Fine
- O : Others

**FORMULATION CODES**

RTU : LIQUID-READY TO USE  
 SC/L : SOLUBLE CONCENTRATE/LIQUID

**ABBREVIATIONS**

AN : As Needed  
 NA : Not Applicable  
 NS : Not Specified (on label)  
 UC : Unconverted due to lack of data (on label)

**APPLICATION RATE**

DNC : Dosage Can Not be Calculated  
 No Calc : No Calculation can be made  
 W : PPM calculated by weight  
 V : PPM calculated by volume  
 CAR : Hundred Weight  
 nxE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

**USE LIMITATIONS CODES**

A08 : Preclean claim.  
 A10 : \_\_\_\_ minute(s) contact time.  
 A11 : \_\_\_\_ hour(s) contact time.  
 A13 : One-step cleaner.  
 A16 : Sterile water rinse.  
 A25 : \_\_\_\_ minute(s) contact time (minimum).  
 A30 : Preclean for heavily soiled areas.  
 C04 : Proper ventilation required.  
 C25 : Remove animals prior to treatment.  
 C27 : Remove feed and water prior to treatment.

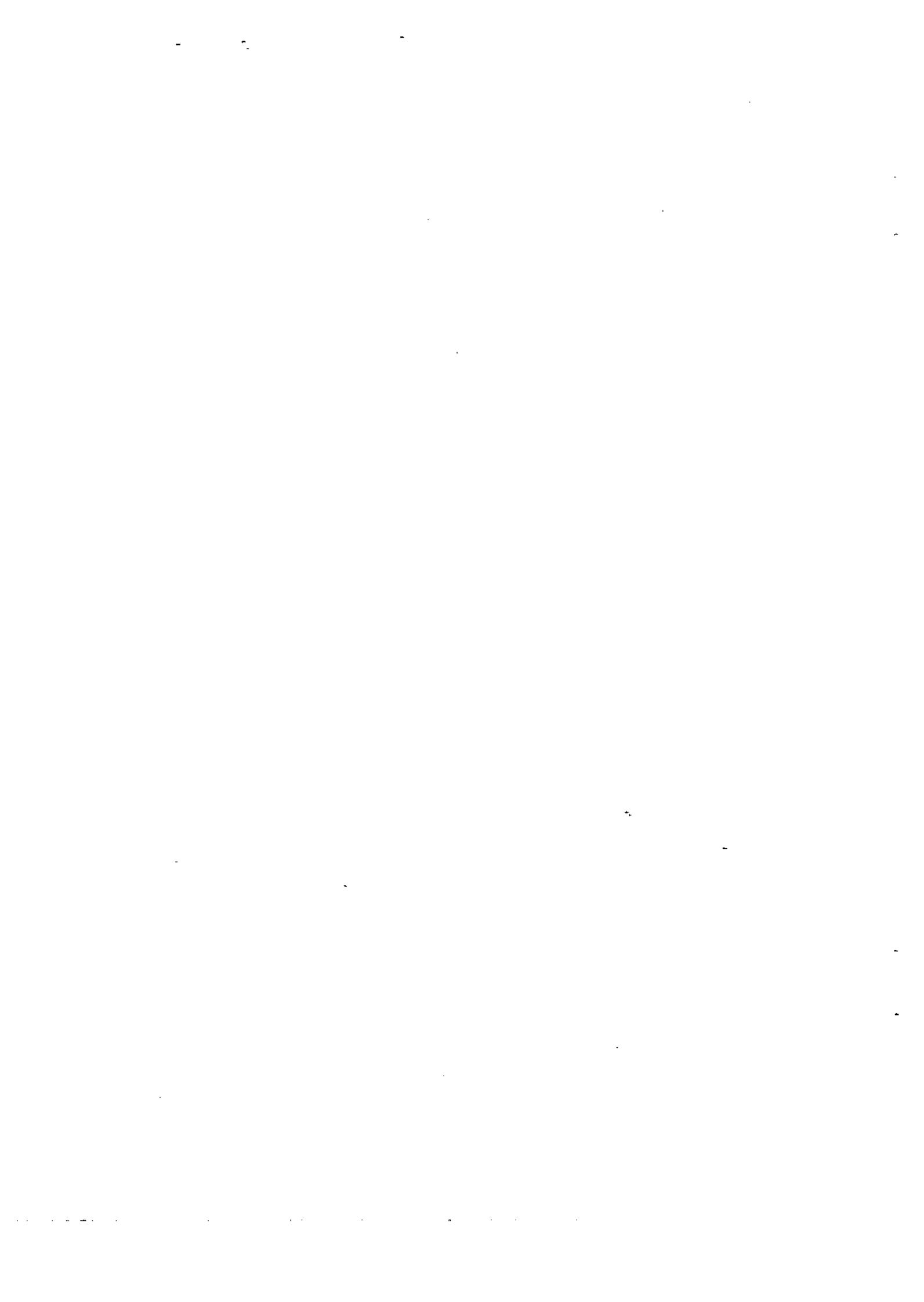
\* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION.

Date 12/09/93 - Time 12:56

APPENDIX A - CASE 4072, [Peroxy crops] Chemical 063201 [Peroxyacetic acid]

SITE Application Type, Application	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr. Geographic	Geographic	Use
Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Application Rate	Application Rates	Text	Apps /crop cycle, @ Max Rate	Interval Allowed or /year (days)	Interval (days)	Entry Interval (days)	Disallowed	Limitations Codes	

Page 1



## USES ELIGIBLE FOR REREGISTRATION

## FOOD/FEED USES

## AGRICULTURAL/FARM PREMISES

Use Group: INDOOR FOOD									
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Premise treatment., Not on label., Not on label., Hard., Not applicable for this use.	SC/L	V 26	*	NS	NS	NS	NS	NS	NS
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Spray-on., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Spray-on., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
AGRICULTURAL/FARM STRUCTURES/BUILDINGS AND EQUIPMENT									
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Premise treatment., Not on label., Not on label., Hard., Not applicable for this use.	SC/L	V 26	*	NS	NS	NS	NS	NS	NS
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	*	NS	NS	NS	NS	NS	NS

**SITE Application Type, Application**

**Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)**

**USES ELIGIBLE FOR PREREGISTRATION****FOOD/FEED USES (con't)****AGRICULTURAL/FARM STRUCTURES/BUILDINGS AND EQUIPMENT (con't)**

Application Rate	Application Rates	Text	App's Max @ Max Dose	Maximum Dose	Min. Restr.	Geographic	Use
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164 *	NS	NS NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164 *	NS	NS NS	NS	A0B, A13, A30, A10(10), A29(500)	
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L V 164	V 164 *	NS	NS NS	NS	A0B, A13, A30, A10(10), A29(500)	

**DAIRIES/CHEESE PROCESSING PLANT EQUIPMENT (FOOD CONTACT)**

Circulation method., Not on label., Not on label., Hard., Not applicable for this use.	SC/L V 103	V 185	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Closed circulation system treatment., Not on label., Hard., Not applicable for this use.	SC/L V 128	V 151	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Not applicable for this use.	SC/L V 103	V 185	*	NS	NS NS	NS	Use Group: INDOOR FOOD

Immersion., Not on label., Not on label., Hard., Not applicable for this use.

Spray., Not on label., Sprayer., Hard., Not applicable for this use.

**DAIRIES/CHEESE PROCESSING PLANT PREMISES (NONFOOD CONTACT)**

Premise treatment., Not on label., Not on label., Hard., Not applicable for this use.	SC/L V 26	V 26	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Brush., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Cloth., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD

**DAIRY CATTLE CLACATING (OR UNSPECIFIED)**

Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD

Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD
Premise treatment., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS NS	NS	Use Group: INDOOR FOOD



SITE Application Type, Application  
Timing, Application Equipment  
Surface Type & Efficacy Influenc-  
ing Factor (Antimicrobial only)

Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Use
Application Rate	Application Rates	Text	Apps Max	Max	crop cycle.	Interv. or /year	Allowed	Geographic	Disallowed
					(days)	(days)			Limitations codes

## USES ELIGIBLE FOR REREGISTRATION

## FOOD/FED USES (con't)

BAIRY GOATS (LIQUIDATING OR UNSPECIFIED) (con't)									
Use Group: INDOOR FOOD (con't)									
Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
EATING ESTABLISHMENTS EQUIPMENT/UTENSILS (FOOD CONTACT)									
Use Group: INDOOR FOOD									
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
EATING ESTABLISHMENTS FOOD HANDLING AREAS (FOOD CONTACT)									
Use Group: INDOOR FOOD									
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION  
FOOD/FEED USES (con't)**

**EATING ESTABLISHMENTS FOOD HANDLING AREAS (FOOD CONTACT) (cont.)**

	Form	Minimum Application Rate	Maximum Application Rates	Text	Maximum Dose	Min.	Restr.	Geographic	Use
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)

**EATING ESTABLISHMENTS FOOD SERVING AREAS (FOOD CONTACT)**

	Form	Minimum Application Rate	Maximum Application Rates	Text	Maximum Dose	Min.	Restr.	Geographic	Use
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)

**FOOD DISPENSING EQUIPMENT/VENDING MACHINES**

	Form	Minimum Application Rate	Maximum Application Rates	Text	Maximum Dose	Min.	Restr.	Geographic	Use
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	A08, A13, A30, A10(10), A29(500)

**SITE Application Type, Application**

Form Minimum

Maximum

Application Rate

Application Rates

Text Max.

Maximum Dose

Min.

Restr.

Geographic

Use

Timing, Application Equipment - Surface type &amp; Efficacy Influencing Factor (Antimicrobial only)

Rate

Max. Dose

Crop cycle, or /year

Interval Entry Interval (days)

(days)

Disallowed

Geographic

Use

**USES ELIGIBLE FOR REREGISTRATION****FOOD/FEED USES (con't)****FOOD DISPENSING EQUIPMENT/VENDING MACHINES (con't)**Scrub., Not on label., Hard., SC/L V 164  
Organic soil (5%).Soak., Not on label., Not on label., Hard., SC/L V 164  
Organic soil (5%).Sponge-on., Not on label., Sponge., Hard., SC/L V 164  
Organic soil (5%).Spray., Not on label., Mechanical sprayer., SC/L V 164  
Hard., Organic soil (5%).Spray., Not on label., Power sprayer., SC/L V 164  
Hard., Organic soil (5%).Wipe-on., Not on label., Cloth., Hard., SC/L V 164  
Organic soil (5%).**FOOD MARKETING/STORAGE/DISTRIBUTION EQUIPMENT/ITEMS (FOOD CONTACT)**Brush-on., Not on label., Brush., Hard., SC/L V 164  
Organic soil (5%).

Mop., Not on label., Mop., Hard., Organic soil (5%).

Scrub., Not on label., Not on label., Hard., SC/L V 164  
Organic soil (5%).Soak., Not on label., Not on label., Hard., SC/L V 164  
Organic soil (5%).Sponge-on., Not on label., Sponge., Hard., SC/L V 164  
Organic soil (5%).Spray., Not on label., Mechanical sprayer., SC/L V 164  
Hard., Organic soil (5%).Spray., Not on label., Power sprayer., SC/L V 164  
Hard., Organic soil (5%).Wipe-on., Not on label., Cloth., Hard., SC/L V 164  
Organic soil (5%).**FOOD GROUP: INDOOR FOOD (con't)**V 164 \* NS  
NS NS NSV 164 \* NS  
NS NS NS**FOOD GROUP: INDOOR FOOD**A0B, A13, A30,  
A10(10), A29(500)A0B, A13, A30,  
A10(10), A29(500)

**SITE Application Type, Application**

Timing, Application Equipment –  
Surface Type & Efficacy Influenc-  
ing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REREGISTRATION****FOOD/FEED USES (con't)****FOOD PROCESSING PLANT EQUIPMENT (FOOD CONTACT)**

	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates	Text	Apps @ Max Dose	/crop cycle, or /year	Interv (days)	Entry Interv (days)	Allowed	Disallowed	Limitations Codes	
<b>USE GROUP: INDOOR FOOD</b>											
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Circulation method., Not on Label., Not on Label., Hard., Not applicable for this use.	SC/L	V 103	V 185	*	NS	NS	NS	NS	NS	A0B, A13, A30, A08, A25(2), A29(500)	
Closed circulation system treatment., Not on Label., Hard., Not applicable for this use.	SC/L	V 128	V 151	*	NS	NS	NS	NS	NS	A0B, A25(1), A34(40)	
Immersion., Not on Label., Not on Label., Hard., Not applicable for this use.	SC/L	V 103	V 185	*	NS	NS	NS	NS	NS	A0B, A13, A30, A08, A25(2), A29(500)	
Scrub., Not on Label., Not on Label., Hard., SC/L	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Spray., Not on Label., Sprayer., Hard., Not applicable for this use.	SC/L	V 103	V 185	*	NS	NS	NS	NS	NS	A0B, A13, A30, A08, A25(2), A29(500)	
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
<b>USE GROUP: NONFOOD CONTACT</b>											
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)	
Premise treatment., Not on Label., Not on Label., Hard., Not applicable for this use.	SC/L	V 26	V 26	*	NS	NS	NS	NS	NS	A0B, A13, A30, A08, A25(5), A29(500)	
Scrub., Not on Label., Not on Label., Hard., SC/L	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	A0B, A13, A30,	



SITE Application Type, Application Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Use
Application Rate	Application Rates	Text	Apps (Max Dose)	/crop cycle, or /year	Interv (days)	Entry Interv (days)	Allowed	Disallowed
Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)							A08, A08, C04, C25, C27, A10(10), A29(500)	Limitations Codes

## USES ELIGIBLE FOR REGISTRATION

## FOOD/FEED USES (con't)

POULTRY (EGG/MEAT) (con't)								
Use Group: INDOOR FOOD (cont'd)								
Premise treatment., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Transportation vehicle treatment., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS

## NON FOOD/NON-FEED

ANIMALS (LABORATORY/RESEARCH)								
Use Group: INDOOR NON-FOOD								
Premise treatment., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Premise treatment., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
BATHROOM PREMISES/HARD SURFACES								
Brush-on, Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS
Mop., Not on Label., Mop., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	*	NS	NS	NS	NS
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 12	V 12	*	NS	NS	NS	NS
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS

**SITE Application Type, Application**

**Timing, Application Equipment -**  
Surface Type & Efficacy Influencing Factor (Antimicrobial only)

Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Graphic	Use
Application Rate	Application Rates	Text	Apps @ Max Rate	/crop cycle, or /year	Interv (days)	Entry Allowed (days)	Disallowed	Limitations Codes		
Scrub., Not on label., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		

**USES ELIGIBLE FOR REREGISTRATION****NON-FOOD/NON-FEED (con't)****BATHROOM PREMISES/HARD SURFACES (cont'd)**

Use Group: INDOOR RESIDENTIAL (cont'd)									
Scrub., Not on label., Not on label., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Soak., Not on label., Not on label., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Sponge-on., Not on label., Sponge., Hard., SC/L	V 1250	V 1250	* NS	NS NS	NS	NS	NS	A08, A10(10), A06	
Sponge-on., Not on label., Sponge., Hard., SC/L	V 12	V 12	* NS	NS NS	NS	NS	NS	A08, A10(5)	
Spray-on., Not on label., Sponge., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Spray-on., Not on label., Mechanical sprayer., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Spray-on., Not on label., Power sprayer., Hard., SC/L	V 164	V 164	* NS	NS NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Spray-on., Not on label., Pump spray bottle., Hard., SC/L	W 600	W 600	* NS	NS NS	NS	NS	NS	A08, A10(0.5)	
Wipe-on., Not on label., Cloth., Hard., Not applicable for this use.	SC/L	V 400	V 400	* NS	NS NS	NS	NS	A10(10)	
Wipe-on., Not on label., Cloth., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	* NS	NS NS	NS	NS	A08, A10(10), A06	
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 12	V 12	* NS	NS NS	NS	NS	A08, A10(5)	
Commercial/Institutional/Industrial Floors									
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	* NS	NS NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Mop., Not on label., Mop., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	* NS	NS NS	NS	NS	A08, A10(10), A06	
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	* NS	NS NS	NS	NS	A08, A13, A30, A10(10), A29(500)	
Scrub., Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	V 164	* NS	NS NS	NS	NS	A08, A13, A30, A10(10), A29(500)	

**SITE Application Type, Application**

Timing, Application Equipment – Surface Type & Efficacy influencing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REGISTRATION****NON FOOD/NON FEED (con't)****COMMERCIAL/INSTITUTIONAL/INDUSTRIAL FLOORS (con't)**

	Form	Minimum Application Rate	Maximum Application Rates (Max Dose)	Text Rate	Apps (Max Dose)	Maximum Dose	Min.	Restr.	Geographic Interv. Allowed (days)	Geographic Interv. (days)	Disallowed	Graphic	Use	
Soak-, Not on label., Not on label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Sponge-on., Not on label., Sponge., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(10), A06		
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Spray-, Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Spray-, Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500), A10(10)		
Spray-, Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	V 400	V 400	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(10)		
Wipe-on., Not on label., Cloth., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(10), A06		
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
<b>COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIP. (INDOOR)</b>														
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Mop-, Not on label., Mop., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(10), A06		
Mop-, Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Scrub-, Not on label., Not on label., Hard., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Soak-, Not on label., Not on label., Hard., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		
Sponge-on., Not on label., Sponge., Hard., Not applicable for this use.	SC/L	V 1250	V 1250	*	NS	NS	NS	NS	NS	NS	NS	A08, A10(10), A06		
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)		

**SITE Application Type, Application**

Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)

**USES ELIGIBLE FOR REGISTRATION****NON-FOOD/NON-FEED (con't.)**

Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
Application Rate	Application Rates (Max Dose)	Text	Apps & Max Rate	/crop cycle, or /year	Interv (days)	Entry (days)	Allotted Interv (days)	Disallowed	Geographic	Use
										Limitations Codes

**COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIP. (INDOOR) (cont'd.)**

Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)	Use Group: INDOOR NON-FOOD (cont'd.)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L V 400	V 400	*	NS	NS	NS	NS	NS	NS	A10(10)
Wipe-on., Not on label., Cloth., Hard., Not SC/L V 1250 applicable for this use.	SC/L V 1250	V 1250	*	NS	NS	NS	NS	NS	NS	A08, A10(10), A06
Wipe-on., Not on label., Cloth., Hard., organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
<b>EATING ESTABLISHMENTS FOOD HANDLING AREAS (NONFOOD CONTACT)</b>										
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Scrub., Not on label., Not on label., Hard., SC/L V 164 Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Soak., Not on label., Not on label., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Sponge-on., Not on label., Sponge., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Spray., Not on label., Power sprayer., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
Wipe-on., Not on label., Cloth., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)
<b>EATING ESTABLISHMENTS FOOD SERVING AREAS (NONFOOD CONTACT)</b>										
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L V 164	V 164	*	NS	NS	NS	NS	NS	NS	A08, A13, A30, A10(10), A29(500)

## SITE Application Type, Application

Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)

## USES ELIGIBLE FOR REREGISTRATION

## NON-FOOD/NON-FEED (con't.)

	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Disallowed	Limitations	Use
<b>NON-FOOD/NON-FEED (con't.)</b>													
<b>EATING ESTABLISHMENTS FOOD SERVING AREAS (NONFOOD CONTACT)</b> (con't.)													
Mop., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Scrub., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
<b>EATING ESTABLISHMENTS NON FOOD AREAS (NONFOOD CONTACT)</b>													
Brush-on., Not on Label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Mop., Not on Label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Scrub., Not on Label., Not on Label., Hard., SC/L V 164, Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Soak., Not on Label., Not on Label., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Sponge-on., Not on Label., Sponge., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Spray., Not on Label., Mechanical sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Spray., Not on Label., Power sprayer., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)
Wipe-on., Not on Label., Cloth., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS		NS	NS	NS	NS	NS	NS	A0B, A13, A30, A10(10), A29(500)

## SITE Application Type, Application Form Minimum

Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)

## USES ELIGIBLE FOR REREGISTRATION

## NON - FOOD/NON - FEED (con't)

## HOSPITAL CRITICAL ITEMS (SURGICAL INSTRUMENTS/PACEMAKERS)

Angioplasty catheter treatment., Not on Label., Not on label., Not Applicable., Not applicable for this use.

Dialyzer treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.

			Maximum Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates	Text (Max Dose)	Apps or Rate	/crop cycle, or /year	Entry (days)	Allowed Interval (days)	Disallowed	Limitations Codes
<b>Use Group: INDOOR MEDICAL</b>									
SC/L	V 400	W 600	W 600	*	NS	NS	NS	NS	A08
SC/L	V 400	W 600	V 400	*	NS	NS	NS	NS	A08, A10(10), A16
SC/L	V 8454	W 2000	V 8454	*	NS	NS	NS	NS	A08, A11(11), A16, A32(75)
SC/L	V 12	W 600	V 12	*	NS	NS	NS	NS	A08
SC/L	V 400	W 600	V 400	*	NS	NS	NS	NS	A08, A10(10), A06, A36(20)
SC/L	V 400	W 600	V 400	*	NS	NS	NS	NS	A08, A11(5.5), A16, A36(20)
SC/L	No Calc	No Calc	No Calc	*	NS	NS	NS	NS	A08, A25(10), A36(20)
<b>Use Group: INDOOR MEDICAL</b>									
SC/L	V 12	W 600	W 600	*	NS	NS	NS	NS	A08, A10(10), A06, A36(20)
SC/L	No Calc	No Calc	No Calc	*	NS	NS	NS	NS	A08, A11(5.5), A16, A36(20)
<b>HOSPITAL NONCRITICAL ITEMS (BEDPANS/FURNITURE)</b>									
SC/L	V 12	W 12	V 12	*	NS	NS	NS	NS	A08, A10(10), A16
SC/L	V 400	W 12	V 400	*	NS	NS	NS	NS	A08, A11(11), A16, A36(20)
SC/L	No Calc	No Calc	No Calc	*	NS	NS	NS	NS	A08, A11(5.5), A16, A36(20)
<b>Use Group: INDOOR MEDICAL</b>									
SC/L	V 12	W 12	V 12	*	NS	NS	NS	NS	A08, A10(10), A06, A36(20)

Immersion., Not on label., Not on label., Hard., Not applicable for this use.

Immersion., Not on label., Not applicable for this use.

## SITE Application Type, Application

Timing, Application Equipment - Surface Type & Efficacy Influen- cing Factor (Antimicrobial only)

## USES ELIGIBLE FOR REREGISTRATION

## NON-FOOD/NON-FEED (con't)

	Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates (Max Dose)	Text Apps Rate	/crop cycle, Max or Max Dose)	Interw. days)	Entry Allowed	Interw. days)	Disallowed	Geographic	Limitations Codes
Immersion., Not on label., Not on label., Hard., Not applicable for this use.	SC/L	W 600	W 600	*	NS	NS	NS	NS	AOB, A25(10), A36(20)	
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 600	W 600	*	NS	NS	NS	NS	AOB, A10(0.5)	

## HOSPITAL/HOSPITAL ITEMS (BEDPANS/FURNITURE) (con't)

	Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates (Max Dose)	Text Apps Rate	/crop cycle, Max or Max Dose)	Interw. days)	Entry Allowed	Interw. days)	Disallowed	Geographic	Limitations Codes
Immersion., Not on label., Not on label., Hard., Not applicable for this use.	SC/L	V 400	V 400	*	NS	NS	NS	NS	A10(10)	
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 600	W 600	*	NS	NS	NS	NS	AOB, A10(10), A06, A36(20)	

## HOSPITAL/SEMICRITICAL ITEMS (CATHETERS/INHALATION EQUIPMENT)

	Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates (Max Dose)	Text Apps Rate	/crop cycle, Max or Max Dose)	Interw. days)	Entry Allowed	Interw. days)	Disallowed	Geographic	Limitations Codes
Immersion., Not on label., Not on label., Hard., Not applicable for this use.	SC/L	V 12	V 12	*	NS	NS	NS	NS	AOB, A11(5.5), A16, A36(20)	
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 600	W 600	*	NS	NS	NS	NS	AOB, A25(10), A36(20)	

## HOSPITAL/MEDICAL INSTITUTIONS: NON CONDUCTIVE FLOORS

	Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates (Max Dose)	Text Apps Rate	/crop cycle, Max or Max Dose)	Interw. days)	Entry Allowed	Interw. days)	Disallowed	Geographic	Limitations Codes
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	W 600	W 600	*	NS	NS	NS	NS	AOB, A10(0.5)	
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	V 400	V 400	*	NS	NS	NS	NS	A10(10)	

## HOSPITALS/MEDICAL INSTITUTIONS: NONCRITICAL PREMISES

	Form	Minimum	Maximum	Soil Max.	Maximum Dose	Min.	Restr.	Geographic	Geographic	Use
	Application Rate	Application Rates (Max Dose)	Text Apps Rate	/crop cycle, Max or Max Dose)	Interw. days)	Entry Allowed	Interw. days)	Disallowed	Geographic	Limitations Codes
Spray., Not on label., Pump spray bottle., Hard., Not applicable for this use.	SC/L	V 400	V 400	*	NS	NS	NS	NS	A10(10), AD6	
Brush-on., Not on label., Brush., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	AOB, A13, A30, A10(10), A29(500)	
Mop., Not on label., Mop., Hard., Organic soil (5%).	SC/L	V 164	V 164	*	NS	NS	NS	NS	AOB, A13, A30, A10(10), A29(500)	
Scrub., Not on label., Not on label., Hard., SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	AOB, A13, A30, A10(10), A29(500)	
Soak., Not on label., Not on label., Hard., SC/L	V 164	V 164	*	NS	NS	NS	NS	NS	AOB, A13, A30, A10(10), A29(500)	

APPENDIX A CASE 4072, [Peroxy compounds] Chemical 0633201 [Peroxyacetic acid]							Page 16
SITE Application Type, Application Form	Minimum	Maximum	Soil Max.	Maximum Dose Min.	Restr. Geographic	Geographic	Use
Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Application Rate	Application Rates	Text Apps	/crop cycle, @ Max Max Dose	Interv Entry or /year (days)	Allowed Interv (days)	Disallowed
							Limitations Codes

**LEGEND****HEADER ABBREVIATIONS**

Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate  
 Min. Interv (days) : Minimum Interval between Applications (days)  
 Restr. Entry Interv (days) : Restricted Entry Interval (days)

**SOIL TEXTURE FOR MAX APP. RATE**

- \* : Non-specific
- C : Coarse
- M : Medium
- F : Fine
- O : Others

**FORMULATION CODES**

RTU : LIQUID-READY TO USE  
 SC/L : SOLUBLE CONCENTRATE/LIQUID

**ABBREVIATIONS**

AN : As Needed  
 NA : Not Applicable  
 NS : Not Specified (on label)  
 UC : Unconverted due to lack of data (on label)

**APPLICATION RATE**

DNC : Dosage Can Not be Calculated  
 No Calc : No calculation can be made  
 W : PPM calculated by weight  
 V : PPM calculated by volume  
 cwt : Hundred Weight  
 nxE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

**USE LIMITATIONS CODES**

A08 : Preclean claim.  
 A10 : — minute(s) contact time.  
 A11 : — hour(s) contact time.  
 A13 : One-step cleaner.  
 A25 : — minute(s) contact time (minimum).  
 A30 : Preclean for heavily soiled areas.  
 C04 : Proper ventilation required.  
 C25 : Remove animals prior to treatment.  
 C27 : Remove feed and water prior to treatment.

\* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.



SITE Application Type, Application	Form	Minimum	Maximum	Soil	Max.	Maximum Dose	Min.	Restr. Geographic	Geographic	Use
Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Application Rate	Application Rate	Application Rates (Max & Max Dose)	Test Apps Rate	Max	/crop cycle, or /year	Interv (days)	Entry Interv (days)	Allowed	Limitations Codes

**LEGEND****HEADER ABBREVIATIONS**

Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate  
 Min. Interv (days) : Minimum Interval between Applications (days)  
 Restr. Entry Interv (days) : Restricted Entry Interval (days)

**SOIL TEXTURE FOR MAX APP. RATE**

- \* : Non-specific
- C : Coarse
- M : Medium
- F : Fine
- O : Others

**FORMULATION CODES**

SC/S : SOLUBLE CONCENTRATE/SOLID ID

**ABBREVIATIONS**

- AN : As Needed
- NA : Not Applicable
- NS : Not Specified (on label)
- UC : Unconverted due to lack of data (on label)

**APPLICATION RATE**

DNC : Dosage Can Not be Calculated  
 No Calc : No calculation can be made  
 W : PPM calculated by weight  
 V : PPM Calculated by volume  
 cwt : Hundred Weight  
 nre:xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

**USE LIMITATIONS CODES**

A03 : Hard water activity  
 A10 : minute(s) contact time.  
 C25 : Remove animals prior to treatment.  
 C27 : Remove feed and water prior to treatment.  
 \* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION.

## **APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision**



## **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Peroxy compounds covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Peroxy compounds in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.



## APPENDIX B

### Data Supporting Guideline Requirements for the Reregistration of Hydrogen peroxide

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY ALL DATA REQUIREMENTS HAVE BEEN WAIVED</b>		
<b>ECOLOGICAL EFFECTS</b>		
71-1A	Acute Avian Oral - Quail/Duck	ALL WAIVED
71-2B	Avian Dietary - Duck	ALL WAIVED
72-1C	Fish Toxicity Rainbow Trout	ALL WAIVED
72-2A	Invertebrate Toxicity	ALL WAIVED
<b>TOXICOLOGY</b>		
81-1	Acute Oral Toxicity - Rat	ALL WAIVED
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL WAIVED
81-3	Acute Inhalation Toxicity - Rat	ALL WAIVED
81-4	Primary Eye Irritation - Rabbit	ALL WAIVED
81-5	Primary Dermal Irritation - Rabbit	ALL WAIVED
81-6	Dermal Sensitization - Guinea Pig	ALL WAIVED
82-3	90-Day Dermal - Rodent	ALL WAIVED
82-4	90-Day Inhalation - Rat	ALL WAIVED
83-3A	Developmental Toxicity - Rat	ALL WAIVED
83-3B	Developmental Toxicity - Rabbit	ALL WAIVED
83-4	2-Generation Reproduction - Rat	ALL WAIVED

## Data Supporting Guideline Requirements for the Reregistration of Hydrogen peroxide

REQUIREMENT	USE PATTERN	CITATION(S)
84-2A Gene Mutation (Ames Test)	ALL	WAIVED
84-2B Structural Chromosomal Aberration	ALL	WAIVED
84-4 Other Genotoxic Effects	ALL	WAIVED
<b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b>	<b>ALL DATA REQUIREMENTS WAIVED</b>	
<b>ENVIRONMENTAL FATE</b>	<b>ALL DATA REQUIREMENTS WAIVED</b>	

# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Peroxyacetic Acid

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY</b>		
<b>ECOLOGICAL EFFECTS</b>		
<b>TOXICOLOGY</b>		
71-1A	Acute Avian Oral - Quail/Duck	ALL WAIVED
71-2B	Avian Dietary - Duck	ALL WAIVED
72-1C	Fish Toxicity Rainbow Trout	ALL WAIVED
72-2A	Invertebrate Toxicity	ALL WAIVED
81-1	Acute Oral Toxicity - Rat	ALL WAIVED
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL WAIVED
81-3	Acute Inhalation Toxicity - Rat	ALL WAIVED
81-4	Primary Eye Irritation - Rabbit	ALL WAIVED
81-5	Primary Dermal Irritation - Rabbit	ALL WAIVED
81-6	Dermal Sensitization - Guinea Pig	ALL WAIVED
82-3	90-Day Dermal - Rodent	ALL WAIVED
82-4	90-Day Inhalation - Rat	ALL WAIVED
83-3B	Developmental Toxicity - Rabbit	ALL WAIVED
83-4	2-Generation Reproduction - Rat	ALL WAIVED
84-2A	Gene Mutation (Ames Test)	ALL WAIVED

**Data Supporting Guideline Requirements for the Reregistration of Peroxyacetic Acid**

REQUIREMENT	USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration	ALL WAIVED
84-4	Other Genotoxic Effects	ALL WAIVED
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>	<u>ALL DATA REQUIREMENTS WAIVED</u>	
<u>ENVIRONMENTAL FATE</u>	<u>ALL DATA REQUIREMENTS WAIVED</u>	

## APPENDIX B

### Data Supporting Guideline Requirements for the Reregistration of Potassium peroxyomonosulfatesulfate

REQUIREMENT	PRODUCT CHEMISTRY	ALL DATA REQUIREMENTS WAIVED	USE PATTERN	CITATION(S)
<b>ECOLOGICAL EFFECTS</b>				
71-1A	Acute Avian Oral - Quail/Duck	ALL	WAIVED	
71-2A	Avian Dietary - Quail	ALL		204057
71-2B	Avian Dietary - Duck	ALL		204058
72-1A	Fish Toxicity Bluegill	ALL		19852
72-1C	Fish Toxicity Rainbow Trout	ALL		19852
72-2A	Invertebrate Toxicity	ALL	WAIVED	
<b>TOXICOLOGY</b>				
81-1	Acute Oral Toxicity - Rat	ALL		42607401
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL		42607402
81-3	Acute Inhalation Toxicity - Rat	ALL		42591201
81-4	Primary Eye Irritation - Rabbit	ALL		42607403
81-5	Primary Dermal Irritation - Rabbit	ALL		42607401
81-6	Dermal Sensitization - Guinea Pig	ALL	WAIVED	
82-1A	90-Day Feeding - Rodent	ALL	WAIVED	
82-3	90-Day Dermal - Rodent	ALL	WAIVED	
83-3A	Developmental Toxicity - Rat	ALL	WAIVED	

**Data Supporting Guideline Requirements for the Reregistration of Potassium peroxyomonosulfatesulfate**

REQUIREMENT	USE PATTERN	CITATION(S)
83-3B	Developmental Toxicity - Rabbit	ALL
83-4	2-Generation Reproduction - Rat	ALL
84-2A	Gene Mutation (Ames Test)	ALL
84-2B	Structural Chromosomal Aberration	ALL
84-4	Other Genotoxic Effects	ALL
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>	<u>ALL DATA REQUIREMENTS WAIVED</u>	
<u>ENVIRONMENTAL FATE</u>	<u>ALL DATA REQUIREMENTS WAIVED</u>	





**APPENDIX C. Citations Considered to be Part of the  
Data Base Supporting the Reregistration of Peroxy  
compounds**



## GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

## BIBLIOGRAPHY

### MRID

### CITATION

---

- Bard, A.J., Parsons, R. and Jordan, J. 1985. Standard Potentials in Aqueous Solutions. IUPAC, Physical and Analytical Chemistry Divisions, Commissions on Electrochemistry and Electroanalytical Chemistry; Marcel Dekker, Inc., New York, NY; pp. 57-58.
- Cotton, F.A., and G. Wilkinson. 1988. Advanced Inorganic Chemistry. John Wiley and Sons, New York. pp. 456-460.
- Greenwood, N.N and Earnshaw, A. 1984. Chemistry of the Elements; Pergamon Press, Oxford, UK; pp. 834-854; 742-748.
- Mortimer, C.E. 1975. Chemistry: A Conceptual Approach. D.Van Nostrand Company, New York. pp. 233-234.
- Turk, A., H. Meislich, F. Brescia, J. Arents. 1968. Introduction to Chemistry. Academic Press, New York. pp.401-402.



## **APPENDIX D. List of Available Related Documents**



The following is a list of available documents related to Peroxy compounds. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Peroxy compounds and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. Peroxy compounds RED Fact Sheet
4. PR Notice 86-5 (included in this appendix)
5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement



## **APPENDIX E. PR Notices 86-5 and 91-2**



**PR Notice 86-5**





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

### PR NOTICE 86-5

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

#### NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

- Attention: Persons responsible for Federal registration of pesticides.
- Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

#### I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

#### II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

#### III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

#### IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

#### V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

#### VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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\*\*\*\*\*

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.
- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

## B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

## C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).
- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

#### C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

<u>Element</u>	<u>When Required</u>	<u>Example</u>
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

## D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

- a. Study title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.
- b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.
- c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.
- d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.
- e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.
- f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).
- g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA  
§10(d) (1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d) (1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d) (1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated; and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D) (1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d) (1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

## D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

### E. Reference to Previously Submitted Data

**DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE** unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

### F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

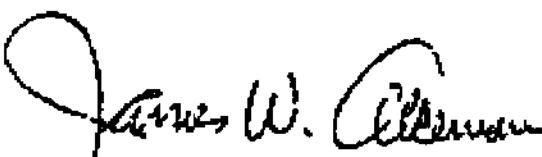
## G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

## V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.



James W. Akerman  
Acting Director,  
Registration Division

- Attachment 1. Sample Transmittal Document
- Attachment 2. Sample Title Page for a Newly Submitted Study
- Attachment 3. Statements of Data Confidentiality Claims
- Attachment 4. Supplemental Statement of Data Confidentiality Claims
- Attachment 5. Samples of Confidential Attachments
- Attachment 6. Sample Good Laboratory Practice Statements
- Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT\*

1. Name and address of submitter (or all joint submitters\*\*)

\*Smith Chemical Corporation  
1234 West Smith Street  
Cincinnati, OH 98765                   -and-                   Jones Chemical Company  
5678 Wilson Blvd  
Covington, KY 56789

\*Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1.     Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2.     Title of first study in the submittal (Guideline No.)

Vol n       Title of nth study in the submittal (Guideline No.)

\*     Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

\*     Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: \_\_\_\_\_

Name

Signature

Company Name: \_\_\_\_\_

Company Contact: \_\_\_\_\_

Name

Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories  
940 West Bay Drive  
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X  
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company \_\_\_\_\_

Company Agent: \_\_\_\_\_ Typed Name \_\_\_\_\_ Date: \_\_\_\_\_

Title \_\_\_\_\_ Signature \_\_\_\_\_

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: \_\_\_\_\_

Company Agent: \_\_\_\_\_ Typed Name \_\_\_\_\_ Date: \_\_\_\_\_

Title \_\_\_\_\_ Signature \_\_\_\_\_

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

## SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.			
DELETED WORDS OR PHRASE:			Ethylene Glycol
PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	\$10(d)(1)(C)
12	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.			
DELETED PARAGRAPH(S) :			
( ) Reproduce the deleted paragraph(s) here			
PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	\$10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a placeholder page is used in place of the following whole pages at the indicated volume and page references.			
DELETED PAGE(S) : are attached immediately behind this page.			
PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the product manufacturing process	\$10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter \_\_\_\_\_

Sponsor \_\_\_\_\_

Study Director \_\_\_\_\_

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Submitter \_\_\_\_\_

Sponsor \_\_\_\_\_

Study Director \_\_\_\_\_

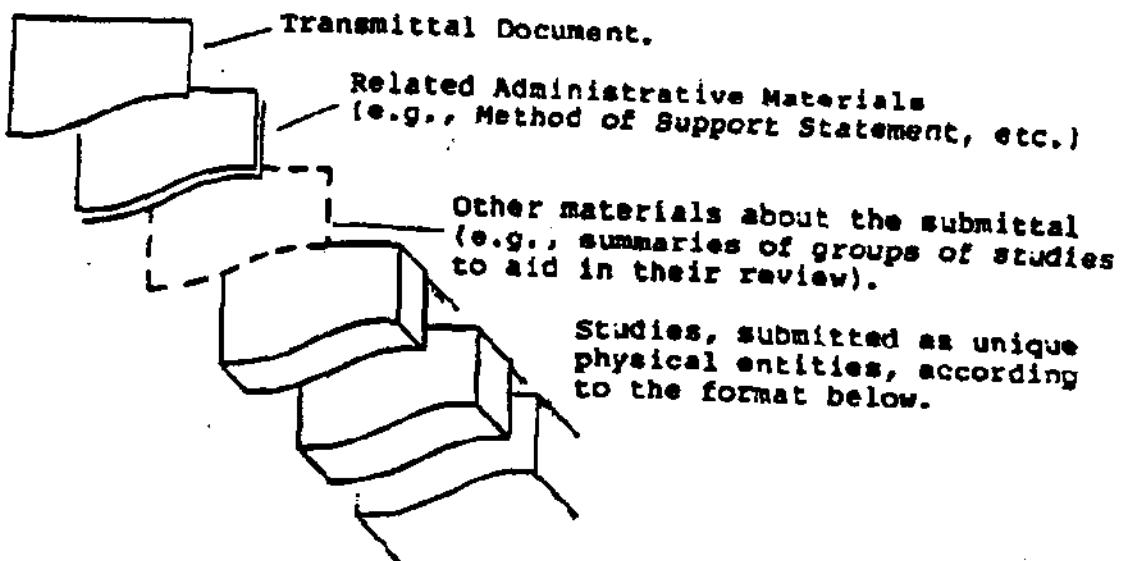
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

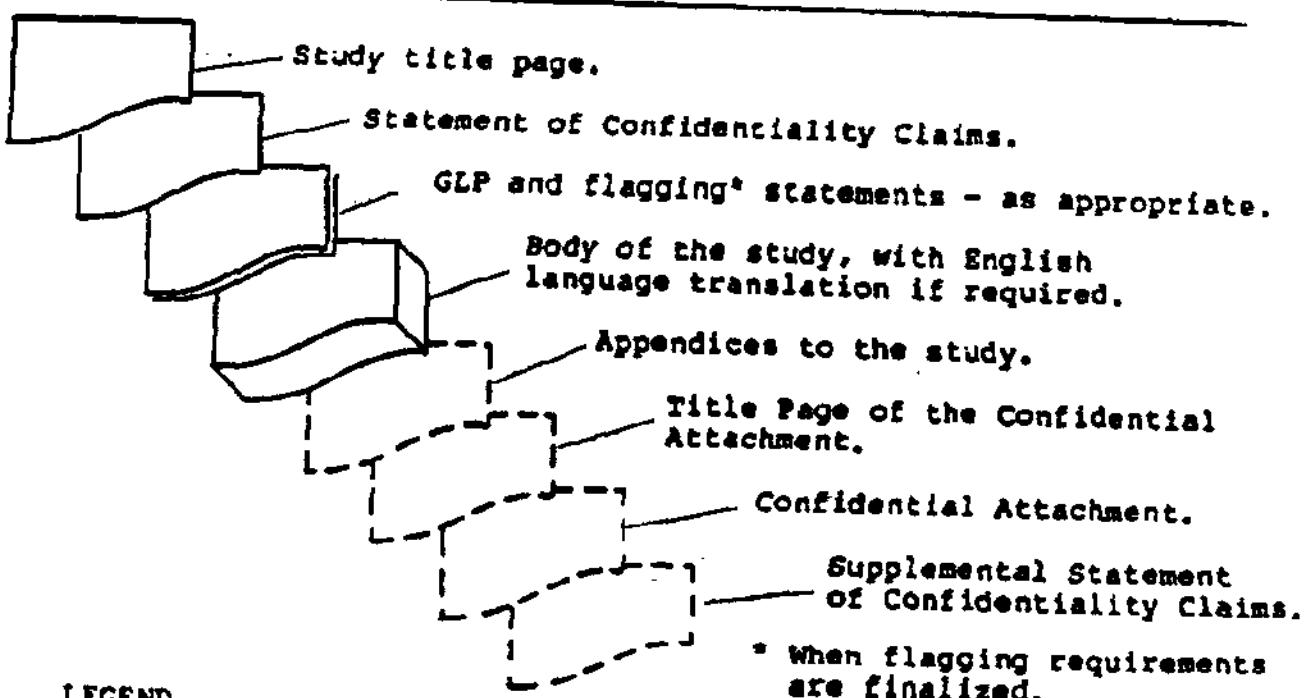
Submitter \_\_\_\_\_

ATTACHMENT 7.

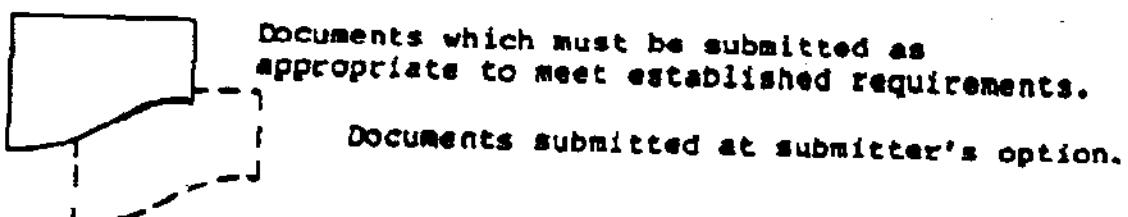
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND





**PR Notice 91-2**





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## PR NOTICE 91-2

### NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of  
Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients  
Statement

#### I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

#### II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

### III. REQUIREMENTS

As described below under Unit V. " COMPLIANCE SCHEDULE," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be set based on representative sampling and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient statements must be changed to nominal concentration.

#### IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower than the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640..

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

#### V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B)). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

- (1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.
- (2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

- (3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

*Anne E. Lindsay*  
Anne E. Lindsay, Director  
Registration Division (H-7505)

## **APPENDIX F. Product Specific Data Call-In**



## DATA CALL-IN NOTICE

### CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains

information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You Are Receiving This Notice
- Section II - Data Required By This Notice
- Section III - Compliance With Requirements Of This Notice
- Section IV - Consequences Of Failure To Comply With This Notice
- Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - EPA Acceptance Criteria
- 6 - List of Registrants Receiving This Notice
- 7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

## **SECTION I. WHY YOU ARE RECEIVING THIS NOTICE**

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

## **SECTION II. DATA REQUIRED BY THIS NOTICE**

### **II-A. DATA REQUIRED**

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### **II-B. SCHEDULE FOR SUBMISSION OF DATA**

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

## **II-C. TESTING PROTOCOL**

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

## **II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY**

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

## **SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE**

### **III-A. SCHEDULE FOR RESPONDING TO THE AGENCY**

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

### **III-B. OPTIONS FOR RESPONDING TO THE AGENCY**

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data

requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the

six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified time frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending

on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice.

Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

## IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or
  - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

#### **IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE**

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

#### SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

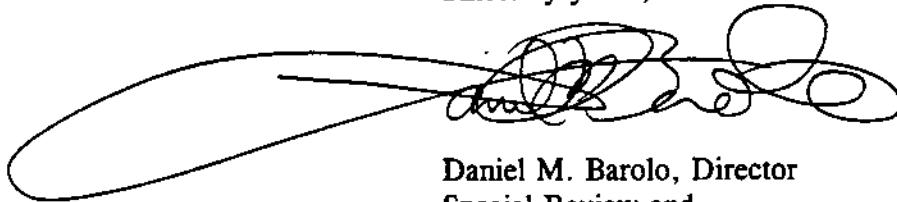
## **SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,



Daniel M. Barolo, Director  
Special Review and  
Reregistration Division

### Attachments

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - EPA Acceptance Criteria
- 6 - List of Registrants Receiving This Notice
- 7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

## **Attachment 1. Chemical Status Sheet**

## **PEROXY COMPOUNDS DATA CALL-IN CHEMICAL STATUS SHEET**

### **INTRODUCTION**

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing peroxy compounds.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of peroxy compounds. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this peroxy compounds Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

### **DATA REQUIRED BY THIS NOTICE**

The additional data requirements needed to complete the database for peroxy compounds are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on peroxy compounds are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible peroxy compounds products.

### **INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the generic database of peroxy compounds, please contact Rieman Rhinehart at (703) 308-8584.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis (703) 308-8184

All responses to this Notice for the Product Specific data requirements should be submitted to:

Accelerated Reregistration Branch, Chemical Review Manager Team 81  
Product Reregistration Branch  
Special Review and Reregistration Branch 7508W  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460

**RE: Peroxy compounds**

**Attachment 2. Product Specific Data Call-In Response  
Forms (Form A inserts) Plus Instructions**



## INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

- Item 1-4. Already completed by EPA.
- Item 5. If you wish to voluntarily cancel your product, answer "yes". If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.
- Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."
- Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." if you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver. See item 6 with regard to identical products and data exemptions.
- Items 8-11. Self-explanatory.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.



**Attachment 3. Product Specific Requirement Status and  
Registrant's Response Forms (Form B inserts) and  
Instructions**



## INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

- Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.
- Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.
- Item 5. The study title associated with the guideline reference number is identified.
- Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.
- Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.
1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.
  2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.
  3. I have made offers to share in the cost to develop data (Offers to Cost Share).

I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver

request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.



**Attachment 4. EPA Batching of End-Use Products for  
Meeting Data Requirements for Reregistration**



**EPA'S BATCHING OF PRODUCTS CONTAINING HYDROGEN PEROXIDE,  
PEROXYACETIC ACID OR POTASSIUM PEROXYMONOSULFATE AS THE ACTIVE  
INGREDIENTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR  
REREGRISTRATION**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredients hydrogen peroxide, peroxyacetic acid and/or potassium peroxymonosulfate, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must

select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredients hydrogen peroxide, peroxyacetic acid and potassium peroxyomonosulfate.

Table 1.

Batch	EPA Reg. No.	Active Ingredient(s)	Formulation Type
1	1677-129	Hydrogen peroxide ... 27.5% Peroxyacetic acid ... 5.8%	Liquid
	52252-1	Hydrogen peroxide ... 27.0% Peroxyacetic acid ... 5.0%	Liquid
	52252-4	Hydrogen peroxide ... 22.1% Peroxyacetic acid ... 4.5%	Liquid
	52252-5	Hydrogen peroxide ... 22.0% Peroxyacetic acid ... 4.5%	Liquid
	52252-6	Hydrogen peroxide ... 22.0% Peroxyacetic acid ... 4.5%	Liquid
	65402-1	Hydrogen peroxide ... 21.7% Peroxyacetic acid ... 5.1%	Liquid
2	52252-2	Hydrogen peroxide ... 0.92% Peroxyacetic acid ... 0.08%	Liquid
	52252-3	Hydrogen peroxide ... 0.92% Peroxyacetic acid ... 0.08%	Liquid
	52252-7	Hydrogen peroxide ... 0.92% Peroxyacetic acid ... 0.08%	Liquid

Table 2 lists those products the Agency was unable to batch. These products were either considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table 2.

EPA Reg. No.	Active Ingredient(s)	Formulation Type
675-39	Hydrogen peroxide ... 6.00% Phosphoric acid ... 0.85%	liquid
875-107	Peroxyacetic acid ... 15.0%	liquid
5749-7	Hydrogen peroxide ... 31.0%	liquid
58779-1	Peroxyacetic acid ... 35.0%	liquid
62432-1	Potassium peroxymonosulfate ... 20.4% Sodium chloride ... 1.5%	solid



## **Attachment 5. EPA Acceptance Criteria**



## **SUBDIVISION D**

<b>Guideline</b>	<b>Study Title</b>
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

## 61 Product Identity and Composition

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. \_\_\_\_\_ Name of technical material tested (include product name and trade name, if appropriate).
2. \_\_\_\_\_ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.
3. \_\_\_\_\_ Name and upper certified limit for each impurity or each group of impurities present at  $\geq 0.1\%$  by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at  $<0.1\%$ .
4. \_\_\_\_\_ Purpose of each active ingredient and each intentionally-added inert.
5. \_\_\_\_\_ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.
6. \_\_\_\_\_ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.
7. \_\_\_\_\_ Description of each beginning material in the manufacturing process.  
\_\_\_\_\_ EPA Registration Number if registered; for other beginning materials, the following:
  - \_\_\_\_\_ Name and address of manufacturer or supplier.
  - \_\_\_\_\_ Brand name, trade name or commercial designation.
  - \_\_\_\_\_ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.
8. \_\_\_\_\_ Description of manufacturing process.  
\_\_\_\_\_ Statement of whether batch or continuous process.  
\_\_\_\_\_ Relative amounts of beginning materials and order in which they are added.  
\_\_\_\_\_ Description of equipment.  
\_\_\_\_\_ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.  
\_\_\_\_\_ Statement of whether process involves intended chemical reactions.  
\_\_\_\_\_ Flow chart with chemical equations for each intended chemical reaction.  
\_\_\_\_\_ Duration of each step of process.  
\_\_\_\_\_ Description of purification procedures.  
\_\_\_\_\_ Description of measures taken to assure quality of final product.
9. \_\_\_\_\_ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at  $\geq 0.1\%$  or was found at  $\geq 0.1\%$  by product analyses and (2) certain toxicologically significant impurities (see #3).

## 62 Analysis and Certification of Product Ingredients

### ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.  Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at  $\geq 0.1\%$ .
2.  Degree of accountability or closure  $\geq$  ca 98%.
3.  Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]
4.  Complete and detailed description of each step in analytical method used to analyze above samples.
5.  Statement of precision and accuracy of analytical method used to analyze above samples.
6.  Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.  Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.  Upper certified limit proposed for each impurity present at  $\geq 0.1\%$  and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.  Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.  Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

## 63 Physical and Chemical Characteristics

### ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

#### 63-2 Color

- Verbal description of coloration (or lack of it)
- Any intentional coloration also reported in terms of Munsell color system

#### 63-3 Physical State

- Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
- Based on visual inspection at about 20-25° C

#### 63-4 Odor

- Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
- Observed at room temperature

#### 63-5 Melting Point

- Reported in °C
- Any observed decomposition reported

#### 63-6 Boiling Point

- Reported in °C
- Pressure under which B.P. measured reported
- Any observed decomposition reported

#### 63-7 Density, Bulk Density, Specific Gravity

- Measured at about 20-25° C
- Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft<sup>3</sup> or lbs/gallon.]

#### 63-8 Solubility

- Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
- Measured at about 20-25° C
- Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

#### 63-9 Vapor Pressure

- Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
- Experimental procedure described
- Reported in mm Hg (torr) or other conventional units

#### 63-10 Dissociation Constant

- Experimental method described
- Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

- \_\_\_\_ Measured at about 20-25° C
- \_\_\_\_ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
- \_\_\_\_ Data supporting reported value provided

63-12 pH

- \_\_\_\_ Measured at about 20-25° C
- \_\_\_\_ Measured following dilution or dispersion in distilled water

63-13 Stability

- \_\_\_\_ Sensitivity to metal ions and metal determined
- \_\_\_\_ Stability at normal and elevated temperatures
- \_\_\_\_ Sensitivity to sunlight determined

## SUBDIVISION F

<u>Guideline</u>	<u>Study Title</u>
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

## **81-1 Acute Oral Toxicity in the Rat**

### **ACCEPTANCE CRITERIA**

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  At least 5 young adult rats/sex/group.
3.  Dosing, single oral may be administered over 24 hrs.
4.  Vehicle control if other than water.
5.  Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.  Individual observations at least once a day.
7.  Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.  Individual daily observations.
9.  Individual body weights.
10.  Gross necropsy on all animals.

Criteria marked with an \* are supplemental and may not be required for every study.

## 81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  At least 5 animals/sex/group.
- 3.\*  Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4.  Dosing, single dermal.
5.  Dosing duration at least 24 hours.
- 6.\*  Vehicle control, only if toxicity of vehicle is unknown.
7.  Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8.  Application site clipped or shaved at least 24 hours before dosing.
9.  Application site at least 10% of body surface area.
10.  Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11.  Individual observations at least once a day.
12.  Observation period to last at least 14 days.
13.  Individual body weights.
14.  Gross necropsy on all animals.

Criteria marked with an \* are supplemental and may not be required for every study.

### **81-3 Acute Inhalation Toxicity in the Rat**

#### **ACCEPTANCE CRITERIA**

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15  $\mu\text{m}$  or less).
3.  At least 5 young adult rats/sex/group.
4.  Dosing, at least 4 hours by inhalation.
5.  Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.  Chamber temperature, 22° C ( $\pm 2^\circ$ ), relative humidity 40-60%.
7.  Monitor rate of air flow.
8.  Monitor actual concentrations of test material in breathing zone.
9.  Monitor aerodynamic particle size for aerosols.
10.  Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.  Individual observations at least once a day.
12.  Observation period to last at least 14 days.
13.  Individual body weights.
14.  Gross necropsy on all animals.

## 81-4 Primary Eye Irritation in the Rabbit

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  Study not required if material is corrosive, causes severe dermal irritation or has a pH of  $\leq 2$  or  $\geq 11.5$ .
3.  6 adult rabbits.
4.  Dosing, instillation into the conjunctival sac of one eye per animal.
5.  Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.  Solid or granular test material ground to a fine dust.
7.  Eyes not washed for at least 24 hours.
8.  Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
- 9.\*  Individual daily observations.

## 81-5 Primary Dermal Irritation Study

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  Study not required if material is corrosive or has a pH of  $\leq 2$  or  $\geq 11.5$ .
3.  6 adult animals.
4.  Dosing, single dermal.
5.  Dosing duration 4 hours.
6.  Application site shaved or clipped at least 24 hours prior to dosing.
7.  Application site approximately 6 cm<sup>2</sup>.
8.  Application site covered with a gauze patch held in place with nonirritating tape.
9.  Material removed, washed with water, without trauma to application site.
10.  Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
- 11.\*  Individual daily observations.

Criteria marked with an \* are supplemental and may not be required for every study.

## 81-6 Dermal Sensitization in the Guinea Pig

### ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.  Identify material tested (technical, end-use product, etc).
2.  Study not required if material is corrosive or has a pH of  $\leq 2$  or  $\geq 11.5$ .
3.  One of the following methods is utilized:
  - Freund's complete adjuvant test
  - Guinea pig maximization test
  - Split adjuvant technique
  - Buehler test
  - Open epicutaneous test
  - Mauer optimization test
  - Footpad technique in guinea pig.
4.  Complete description of test.
- 5.\*  Reference for test.
6.  Test followed essentially as described in reference document.
7.  Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an \* are supplemental and may not be required for every study.

**Attachment 6. List of All Registrants Sent This Data Call-In (insert)  
Notice**



**Attachment 7. Cost Share Data Compensation Form, and Confidential  
Statement of Formula Form**



**Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)**

Form Approved, OMB No 2070-0080. Approval Expires 2/26/94



United States Environmental Protection Agency  
Office of Pesticide Programs (TS-761)  
Washington, DC 20460

**Confidential Statement of Formula**

1. Name and Address of Applicant/Registrant [Include ZIP Code]

		A <input type="checkbox"/> Basic Formulation <input type="checkbox"/> Alternate Formulation		B					
		2. Name and Address of Producer [Include ZIP Code]				See Instructions on Back			
3. Product Name		4. Registration No./File Symbol		5. EPA Product No./Item No.		6. Country Where Formulated			
		7. Pounds/Gal or Bulk Density		8. pH		9. Flash Point/Fire Extension			
EPA USE ONLY	10. Components in formulation /List as actually introduced into the formulation. Give common name accepted chemical name, trade name, and CAS number/		11. Supplier Name & Address		12. EPA Reg. No.		13. Each Component in Formulation a. Amount	14. Certified Limits a. % by Weight b. % by Volume c. Upper Limit & Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official		17. Total Weight		100%					
18. Signature of Approving Official		19. Title		20. Phone No. (Includes Area Code)		21. Date			
						Yellow - Applicant copy			



## **Instructions for Completing the Confidential Statement of Formula**

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inert and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.





United States Environmental Protection Agency  
Washington, DC 20460  
**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106  
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer
-----------------	---------------

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete





United States Environmental Protection Agency  
Washington, DC 20460  
**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

Form Approved

OMB No. 2070-0107

2070-0087

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

- The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

**GENERAL OFFER TO PAY:** I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-80)

